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Guidance for the Reregistration of Pesticide Products Containing Aldrin as the Active Ingredient

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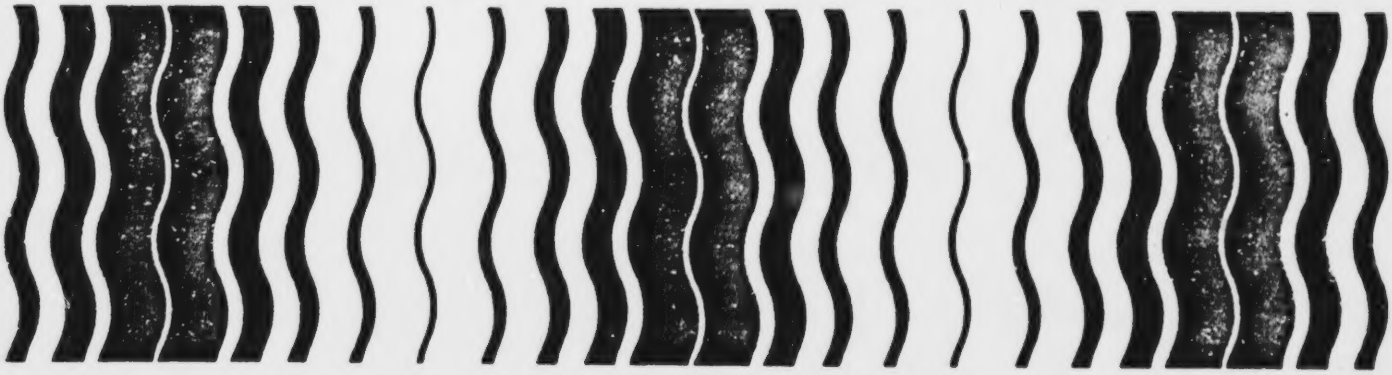

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GUIDANCE FOR THE REREGISTRATION OF PESTICIDE PRODUCTS CONTAINING

ALDRIN

AS THE ACTIVE INGREDIENT

Case No. 0172

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS
WASHINGTON, D.C. 20460

December 31, 1986

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I. INTRODUCTION

The Registration Standards Program

EPA has established the Registration Standards program in order to provide an orderly mechanism by which pesticide products containing the same active ingredient can be reviewed and standards set for compliance with FIFRA. The standards are applicable to reregistration and future applications for registration of products containing the same active ingredient. Each registrant of a product containing an active ingredient subject to this Standard who wishes to continue to sell or distribute that product must bring his product and labeling into compliance with FIFRA, as instructed by this Standard. Pesticides have been grouped into use clusters and will be reviewed on the basis of a ranking scheme giving higher priority to (1) pesticides in clusters used on food and feed crops; and (2) pesticides produced in large volumes.

The Registration Standards program involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA. In its review EPA identifies:

1. Studies that are acceptable to support the data requirements for the currently registered uses of the pesticide.

2. Additional studies necessary to support continued registration. The additional studies may not have been required when the product was initially registered or may be needed to replace studies that are now considered inadequate.

3. Labeling revisions needed to ensure that the product is not misbranded and that the labeling is adequate to protect man and the environment.

The detailed scientific review, which is not contained in this document, but is available upon request[1], focuses on the pesticide active ingredient. The scientific review primarily discusses the Agency's evaluation of and conclusions from available data in its files pertaining to the pesticide active ingredient. However, during the review of these data the Agency is also looking for potential hazards that may be associated with the end use products that contain the active ingredient. The Agency will apply the provisions of this Registration Standard to end use products if necessary to protect man and the environment.

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[1] The scientific reviews may be obtained from the Information Services Section, Program Management and Support Division (TS-757C), EPA, 401 M St., SW, Washington, D.C. 20460.

EPA's reassessment results in the development of a regulatory position, contained in this Registration Standard, on the pesticide and each of its registered uses. See Section IV - Regulatory Position and Rationale. Based on its regulatory position, the Agency may prescribe a variety of steps to be taken by registrants to maintain their registrations in compliance with FIFRA. These steps may include:

1. Submission of data in support of product registration;

2. Modification of product labels;

3. Modifications to the manufacturing process of the pesticide to reduce the levels of impurities or contaminants;

4. Restriction of the use of the pesticide to certified applicators or other specially trained individuals;

5. Modification of uses or formulation types; or

6. Specification of packaging limitations.

Failure to comply with these requirements may result in the issuance of a Notice of Intent to Cancel or a Notice of Intent to Suspend (in the case of failure to submit data).

In addition, in cases in which hazards to man or the environment are identified, the Agency may initiate a special review of the pesticide in accordance with 40 CFR Part 154 to examine in depth the risks and benefits of use of the pesticide. If the Agency determines that the risks of the pesticide's use outweigh the benefits of use, the Agency may propose additional regulatory actions, such as cancellation of uses of the pesticide which have been determined to cause unreasonable adverse effects on the environment.

EPA has authority under the Data Call-In (DCI) provisions of FIFRA sec. 3(c)(2)(B) to require that registrants submit data to answer our questions regarding the chemical, toxicological, and environmental characteristics and fate of a pesticide. This Registration Standard lists the data EPA believes are necessary to resolve our concerns about this pesticide. These data are listed in the Tables A, B, and C in Appendix I. Failure to comply with the DCI requirements enumerated in this Registration Standard may result in issuance by EPA of a Notice of Intent to Suspend the affected product registrations.

Registrants are reminded that FIFRA sec. 6(a)(2) requires them to submit factual information concerning possible unreasonable adverse effects of a pesticide at any time that they become aware of such information. You should notify the Agency of any information, including interim or preliminary results of studies, if those results suggest possible adverse effects on man or the environment. This requirement continues as long as your products are registered by the Agency.

II. CHEMICAL COVERED BY THIS STANDARD

A. DESCRIPTION OF CHEMICAL

The following chemical is covered by this Registration Standard:

Common name: Aldrin

Chemical name: 1,2,3,4,10,10-hexachloro-1,4,4a,5,8,8a-hexahydro-exo-1,4-endo-5,8-dimethanonaphthalene

Other names: Aldrine (France), HHDN (Great Britain), Aldrex®, Aldrex 30®, Aldrite®, Aldrosol®, Altox (All Indian Medical), Bangald® (Bangalore Pesticides), Drinox®, Octalene® (Velsicol Chemical Corp.), Rasayaldrin® (Krishi Rasayan), Seedrin® Liquid (discontinued by Rhone-Poulenc, Inc.), Entoma 15949, and Compound 118

CAS Registry number: 309-00-2

EPA Pesticide Chemical Code (Shaughnessy) number: 045101

Physical characteristics:
Empirical Formula: $C_{12}H_8Cl_6$
Molecular weight: 364.93
Color: tan to dark brown (technical)
Physical state: crystalline solid
Odor: mild chemical odor
Melting point: 104 to 105.5 °C
Boiling point: decomposes at 1 atm.
Solubility: very soluble in most organic solvents; practically insoluble in water
Density: 100 lb/cu ft
Vapor pressure: 6.6×10^{-6} mmHg at 25°C
Stability: stable with alkali and alkaline-oxidizing agents. Reacts with concentrated mineral acids, acid catalysts, acid-oxidizing agents, phenols, and active metals.

B. REGULATORY HISTORY

Aldrin was first synthesized as a pesticide in 1948; its major metabolite and epoxidation product, dieldrin, is also a pesticide in its own right. Aldrin and dieldrin received registration approval for use in the U.S. in 1949, under the early FIFRA. In general, the regulatory histories of aldrin and dieldrin have been closely parallel. Until 1974, both aldrin and dieldrin were extensively used as broad-spectrum insecticides on corn and a wide range of other agricultural crops. Both chemicals also had a number of non-agricultural uses including termite control.

In 1974, the EPA Administrator suspended nearly all uses of aldrin and dieldrin for reasons that primarily included the cancer risks posed by both compounds, based on laboratory evidence considered together with exposure information available to EPA at that time (39 FR 37246). Other grounds for the 1974 aldrin/dieldrin suspension order included the persistence of dieldrin residues in the environment, and the bioaccumulation of dieldrin through the food chain. Based on monitoring data collected by EPA, it was estimated that in 1970, 99.5 percent of the human population in the U.S. had dieldrin residues in their tissues. Although aldrin is not very persistent in the form of the parent compound, it readily converts to dieldrin in the environment and in biological systems including the human body. In addition to the human health risks associated with aldrin and dieldrin, evidence showed that endangered species such as the bald eagle were at risk from exposure to dieldrin.

All uses subject to the suspension order, including all food uses, were ultimately cancelled. Tolerances for aldrin and dieldrin were not revoked at the time of their cancellation in 1975 for food and feed uses because of the persistence of aldrin/dieldrin in the environment and the resultant expectation that residues would be present in raw agricultural commodities for a significant time period. However, EPA is now proceeding with the revocation of these tolerances, to be replaced by action levels for unavoidable residues resulting from environmental contamination, in accordance with a September 1982 agreement among the Food and Drug Administration (FDA), the U.S. Department of Agriculture (USDA), and EPA entitled "Policy Statement on the Revocation of Tolerances for Cancelled Pesticides" (47 FR 42956).

On March 13, 1985 (50 FR 10080), EPA published a proposed rule under the Federal Food, Drug, and Cosmetic Act (FFDCA) to revoke all tolerances for residues of aldrin and dieldrin in or on food and feed commodities. The final rule effecting the revocation of these tolerances is scheduled for publication in the Federal Register in early 1987. There are also several existing action levels for aldrin/dieldrin that were previously adopted by the

Food and Drug Administration (FDA) to cover unavoidable residues in food and feed commodities where no tolerances had been established. In conjunction with the revocation of tolerances for aldrin and dieldrin, EPA is recommending that most of these action levels be retained without modification (see section III.D of this Registration Standard).

Three uses of aldrin and dieldrin were specifically exempted from EPA's suspension and cancellation actions because they were believed to result in insignificant exposure and, consequently, insignificant risk. Thus, the registrations of aldrin and dieldrin were retained for subterranean termite control and for two minor uses (the dipping of roots and tops of non-food plants, and moth-proofing in manufacturing processes using totally enclosed systems) that were subsequently cancelled voluntarily at the request of the registrant.

More recently, the termiticide use of aldrin, dieldrin, and other pesticides registered for termite control was subject to a preliminary review of risks and benefits conducted by EPA, with findings presented in a November 1983 report, "Analysis of the Risks and Benefits of Seven Chemicals Used for Subterranean Termite Control." This review of the termiticides was in part prompted by a General Accounting Office (GAO) report entitled "Need for a Formal Risk/Benefit Review of the Pesticide Chlordane," which specifically cited contamination problems discovered in U.S. Air Force military housing where chlordane, the most widely used termiticide chemical, had been applied for termite prevention and control. Rather than focusing solely on chlordane, EPA took the more comprehensive approach of reviewing available risk and benefit data on the various termiticide alternatives (aldrin, dieldrin, heptachlor, lindane, pentachlorophenol, and chlorpyrifos), as well as chlordane. In summary, the Agency found that the benefits of the termiticides, particularly the chlorinated cyclodienes (chlordane, heptachlor, aldrin, and dieldrin), were generally very high, but definitive health and exposure data were lacking to support risk assessments for regulatory purposes.

As an interim regulatory measure early in its review of the termiticides, EPA initiated, in 1981, a Label Improvement Program (LIP) intended to reduce the potential risks of termiticide use primarily by reducing the possibility of misapplication that may result in contamination of treated structures and high exposures to occupants. For aldrin and other termiticide products, required label changes included specific precautions concerning application near vulnerable areas such as domestic water supplies (cisterns, private wells, etc.), near heating ducts, and around structures with sub-floor crawl spaces, and warnings against routine (yearly) retreatment.

Following the issuance of the 1983 report, "Analysis of the Risks and Benefits of Seven Chemicals Used for Subterranean Termite Control," EPA issued, early in 1984, a Special Data Call-In for termiticides requiring registrants to provide the following chemical-specific studies to support a more comprehensive risk assessment of each termiticide:

- A one-year indoor air monitoring study in homes of various construction types, treated for subterranean termite control in accordance with label instructions as revised by EPA's termiticide LIP
- General metabolism studies, one in rats and one in mice, giving special consideration to pharmacokinetics
- Five short-term mutagenicity (gene mutation) assays
- A subchronic inhalation study in rats to assess the potential toxic response from the inhalation route of exposure

The status of these data requirements for aldrin is as follows.[1] The 90-day pilot phase of the aldrin indoor air monitoring study has been completed, and these preliminary results have been reviewed by EPA and are discussed in this Registration Standard. The metabolism data required from the registrant have also been submitted and reviewed. However, the mutagenicity data requirements have not been fully satisfied, and additional mutagenicity studies are being required under this Standard. The registrant requested a waiver of the requirement for a subchronic inhalation study in rats on the grounds that existing data from oral feeding studies could be used for the purpose of assessing the toxic response (other than carcinogenicity) from respiratory exposure to aldrin. A waiver was granted for this particular data requirement (see section III.B.2 of this Standard).

Finally, it should be noted that EPA's Office of Water Regulations and Standards has recommended water quality criteria, under section 304 of the Clean Water Act, for ambient water concentrations of aldrin and dieldrin. EPA issues such criteria under section 304(a) of the Clean Water Act, which requires the Agency to publish criteria for water quality reflecting current scientific knowledge on the kind and extent of all identifiable effects on health and welfare which may be expected from the presence of pollutants in any body of water, including ground water. These ambient water quality criteria are non-regulatory in that they do not in themselves represent enforceable regulatory standards. However, they may be adopted, with or without modification, by individual States and may thus become enforceable State water quality standards. Typically, States may modify EPA's criteria to reflect local environmental conditions and human exposure patterns.

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[1] The registrants of dieldrin declined to sponsor the requisite data. As a result, registrations of all termiticide products containing dieldrin were suspended in 1984.

The ambient water quality criteria recommended for aldrin and their supporting scientific assessments are described in an October 1980 document, "Ambient Water Quality Criteria for Aldrin/Dieldrin (EPA 440/5-80-019)," which is publicly available through the National Technical Information Service (NTIS), Springfield, Virginia 22161 (telephone: 703-487-4650). Specific criteria, expressed as maximum concentration levels per liter of water, are recommended (1) for protection of fresh-water and salt-water aquatic life from acute toxic effects of aldrin and dieldrin, and (2) for protection of human health from potential carcinogenic effects due to exposure to aldrin and dieldrin through ingestion of contaminated water or contaminated aquatic organisms.

C. USE PROFILE

The sole registered use of aldrin in the U.S. is for control of subterranean termites. Aldrin was previously manufactured and sold in this country by Shell Chemical Company. Following EPA's 1974 suspension and subsequent cancellation of most uses of aldrin, Shell discontinued domestic production, and technical aldrin has been imported from abroad, from Shell International, for formulation and use in the U.S. Imports of aldrin ceased temporarily in 1979 and 1980, then resumed in 1981 through 1985. Between 1981 and 1985, an estimated 1.0 to 1.5 million pounds of aldrin active ingredient were used annually, representing roughly 20 to 25% of the total termiticide market during those years. According to information provided to EPA, aldrin has not been imported since 1985, and current usage depends on the volume of available stocks.

Aldrin is used for subterranean termite control either as a pre-construction treatment for preventing termite problems or as a post-construction, remedial treatment. The termiticide is typically applied along the inside and outside of foundations; around the bases of supporting piers, chimney bases, plumbing and conduits; under filled porches, entrances and terraces; under floor structures resting on soil or gravel fill; and exposed soil areas under structures. In pre-construction treatments, aldrin may be applied using a low-pressure spray, before slabs are poured, creating a chemical barrier between potential or existing termite colonies in the soil and wooden construction materials. Post-construction treatment methods include techniques such as "trenching," "rodding," and the drilling of holes in slabs and foundation walls for the purpose of injecting the termiticide.

There are ten federally registered end-use products containing aldrin. All but one of these products, which are formulated into two- or four-pound per gallon emulsifiable concentrates, are currently labeled for use only by commercial pest control operators. There is one federally registered formulation intermediate product. There are no "special local need" registrations under FIFRA section 24(c), and no intrastate products.

III. AGENCY FINDINGS

A. SUMMARY

The Agency has reviewed all data currently supporting the registration of aldrin. Based on the available data, EPA has reached the following conclusions. Many of these conclusions are preliminary where additional data are required under this Registration Standard. The points summarized below are presented in further detail, in the context of EPA's science findings and additional data requirements, in Sections B through D below.

1. Aldrin appears to be acutely toxic through oral and dermal exposure, based on a review of summary reports which do not satisfy EPA data requirements. Additional data are required to fully assess the acute oral, dermal, and inhalation toxicity of aldrin. In addition, special product-specific subacute inhalation testing is required to evaluate the potential of aldrin, the formulation solvent(s), or the aldrin/solvent combination to cause irritation of mucous membranes.

2. The Agency has concluded that aldrin does not cause acute delayed neurotoxic effects.

3. Aldrin exposure may pose a significant health risk of chronic liver effects to occupants of structures treated with aldrin. Based on preliminary (90-day) exposure data from an ongoing indoor air monitoring study, the risk from long-term exposure to ambient air levels of aldrin in buildings treated in accordance with label directions has been roughly estimated to exceed EPA's revised Provisional Acceptable Daily Intake (PADI) for aldrin by three- to seven-fold.

4. The termiticide use of aldrin also poses an oncogenic risk of regulatory concern, based on preliminary risk estimates using the pilot air monitoring exposure data now available. Aldrin is clearly oncogenic in laboratory mice; the available test data in rats are inconclusive and inadequate for assessing the oncogenicity of aldrin in the rat species. In mouse studies separately conducted by independent investigators, aldrin has induced tumors in three strains of mice, with dose-related increases in the proportion of malignancies. EPA will be considering the indoor air monitoring data in determining whether human exposure from the termiticide use of aldrin may be posing risks of cancer and chronic liver effects that may warrant regulatory action.

5. Laboratory data show that technical aldrin is very highly toxic to warm- and cold-water fish species, and to freshwater invertebrates. Aldrin is also characterized as very highly toxic to birds.

6. The termiticide use of aldrin does not appear to result in exposures that threaten any endangered species.

7. The pesticide chlordane, an alternative termiticide, has been found at significant levels in urban lakes in Iowa; preliminary evidence indicates that the source of this contamination may be surface water run-off from the termiticidal use of chlordane. These preliminary findings on chlordane raise the question whether the termiticide use of aldrin could be contaminating surface water. Chlordane and aldrin, both of which are chlorinated cyclodiene pesticides, have similar physical and chemical properties as well as similar application patterns. Therefore, it is reasonable to expect that they may have comparable behavior patterns in the environment.

   For this reason, the Agency is requiring a special study to determine whether aldrin's use as a termiticide may be contaminating surface water. This study is intended to provide information on (1) whether the termiticide use of aldrin is resulting in residues of aldrin and its metabolite dieldrin in drinking water and in fish for human consumption, and (2) whether fish and freshwater invertebrates are at risk of being exposed to toxic levels of aldrin and dieldrin as a result of the termiticide use of aldrin.

8. Data available to EPA show a recurrence of misuse and misapplication of aldrin termiticide products. Improper application practices may result in contamination of air systems in treated structures and unnecessarily high long-term ambient air exposure to occupants of these structures. Moreover, the improper use of aldrin has the potential to result in environmental contamination. The incidence of misapplication and misuse can be reduced by restricting the use of aldrin products to Certified Applicators or persons under their direct supervision, as specifically defined in label provisions prescribed by EPA in this Registration Standard.

As a result of this Registration Standard review, the Agency has determined that certain additional or revised label restrictions are necessary. These include:

- Restricted use classification
- Pesticide disposal procedures
- Fish and wildlife toxicity warnings
- Statement on carcinogenic and adverse liver effects in laboratory animals.

The Agency has also identified missing data necessary to fully evaluate the human and environmental risks associated with the use of aldrin as a termiticide. These data must be developed in order to maintain registrations of existing products or register any new products containing aldrin. A summary of these data gaps is given in Table 1. Please note that this is only a summary and complete details can be obtained by referring to the tables in Appendix I.

EPA will continue to evaluate the termiticide use of aldrin in terms of the regulatory concerns identified in this Registration Standard as additional information becomes available. The Agency will continue to evaluate the risk of chronic liver effects in humans from exposure to aldrin and also its potential oncogenicity and determine whether additional regulatory action is warranted.

The Regulatory Position and Rationale section of this Registration Standard discusses the Agency's position on each of the regulatory issues concerning aldrin, and the Required Labeling section contains the specific wording required for each of the labeling provisions.

TABLE 1. SUMMARY OF DATA GAPS

(Please refer to the tables in Appendix 1 for detailed information regarding these requirements)

Toxicology

Acute oral toxicity -- rats
Acute dermal toxicity -- rabbits
Acute inhalation toxicity -- rats
Primary eye and dermal irritation studies
Special (product-specific) subacute inhalation toxicity testing -- guinea pigs
Oncogenicity -- rats
Mutagenicity studies
Teratogenicity -- rats and rabbits
Reproductive effects -- rats (2-generation)

Environmental Fate/Exposure*

Hydrolysis study
Aerobic and anaerobic soil metabolism studies
Aerobic aquatic metabolism study
Leaching and adsorption/desorption study
Soil dissipation: field study
Photodegradation in water
Special monitoring study of aldrin residues entering surface water from sanitary sewers, sumps, and drainage tiles from home foundations known to have been properly treated with aldrin
Applicator exposure studies

[Pending results of required environmental fate data, monitoring of residues of aldrin in aquatic sites and chronic fish and wildlife toxicity studies may be required]

Product Chemistry

All product chemistry studies

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* An indoor air exposure monitoring study is currently underway, as required through a special data call-in issued by EPA in February 1984.

B. PRELIMINARY HEALTH RISK ASSESSMENT

Numerous data gaps exist for aldrin and few definitive conclusions can be made pending receipt of additional data. The following assessment is based on the data available and is therefore subject to change.

1. Acute Toxicity. Adequate data are not available to fully assess the acute toxicity of aldrin and additional studies are therefore required on acute oral, dermal, and inhalation toxicity. The published literature suggests that aldrin is relatively toxic when ingested. Reported signs of acute intoxication are primarily related to the central nervous system (CNS) and include hyperexcitability, convulsions, depression, and death. Summary data reports submitted to EPA indicate an acute oral toxicity value for technical aldrin of approximately 46 and 49 mg/kg/body weight in male and female rats, respectively; and a minimum lethal dosage for dermal toxicity ranging from 600 to 1250 mg/kg/body weight (0072077). These values, if confirmed, would place aldrin in Toxicity Category I on the basis of acute oral toxicity, and Toxicity Category II on the basis of dermal toxicity. However, since supporting data are not available to verify these summary reports, they are considered supplementary information and, thus, are inadequate to satisfy EPA's acute toxicity data requirements.

   There have been numerous incidents of acute intoxications in humans from aldrin exposure among chemical plant workers; however, recovery has been complete and relatively rapid following removal from the exposure area. Based on direct human evidence from these incidents, and the dissimilarity of aldrin to known neurotoxic agents (i.e., organophosphates), the Agency has concluded that aldrin does not cause acute delayed neurotoxic effects. For this reason, a delayed neurotoxicity study is not required.

   The Agency has also concluded that aldrin is not a skin sensitizer, again based on human exposure data compiled without reported dermal sensitization. The data supporting this conclusion concern chemical plant workers who experienced the kind of repeated skin contact which is simulated in dermal sensitization studies under laboratory conditions.

   However, product-specific data are required so that EPA may assess the potential of aldrin products to cause primary eye and dermal irritation. The purpose of the requisite primary dermal irritation testing is to determine the irritant or corrosive effects of a single dermal exposure at a dose level that is considerably higher than the dosage used in skin sensitization testing. The results of these primary eye and dermal irritation studies will be considered together with the results of required acute toxicity testing in determining the appropriate toxicity category for aldrin.

In addition, special subacute, product-specific inhalation testing with guinea pigs is being required under this Standard to evaluate the potential of aldrin, the formulation solvent(s), or the aldrin/solvent combination to cause irritation of mucous membranes. This requirement arises from complaints received from persons reporting upper respiratory problems following the treatment of their residence for termite control.

2. Subchronic Toxicity. As noted previously in Section II.B, a subchronic (90-day) inhalation study in rats was among the studies originally required by EPA through the Special Data Call-In issued for aldrin in February 1984. The registrant requested a waiver of this requirement on the grounds that (1) the oral intake of aldrin had been extensively studied, and (2) the data from oral feeding studies indicate that when orally administered, aldrin is almost totally absorbed by the body; the results of long-term oral testing thus represent a worst-case evaluation which could be used in lieu of data from an inhalation study. EPA granted a waiver of this particular requirement on this basis.

In available short-term (subchronic) feeding studies with rats and mice, the major toxic effects exerted by aldrin were reported to be mortality, depressed body weight, increased liver-to-body weight ratios, and histopathological changes in the liver known as chlorinated hydrocarbon insecticide rodent liver (CHIRL) (GS0172-001). The subchronic studies on file with the Agency are considered inadequate to satify EPA's guideline requirements. However, the Agency is not requiring a subchronic feeding study on aldrin, since existing chronic feeding data are adequate for the purpose of defining the liver as the target organ for toxic action, and are sufficient to supercede the need for additional subchronic feeding data.

Pending the results of the acute dermal toxicity study which is required, the requirement for a 21-day dermal study is reserved.

3. Chronic Toxicity: Liver Effects. Administration of aldrin in chronic and subchronic feeding studies in mice and rats has resulted in cellular degeneration and histopathological changes in the liver known as chlorinated hydrocarbon insecticide rodent liver (CHIRL). CHIRL has occurred at doses as low as 0.5 parts per million (ppm), or 0.025 milligrams per kilogram body weight per day (mg/kg/day), the lowest dose tested in a two-year rat feeding study (GS0172-001). Based on this lowest effect level (LEL) of 0.025 mg/kg/day, EPA has calculated a provisional acceptable daily intake (PADI) level for aldrin of 3 x 10^{-5} mg/kg/day, applying a 1,000-fold uncertainty factor. This calculated estimate is provisional because the existing data base for aldrin is lacking the following toxicology data: rat reproduction study, rat teratology study, and rabbit teratology study. The PADI for aldrin of 3 x 10^{-5} represents a revision of a previously calculated PADI of 2.5 x 10^{-4} mg/kg/day, based on 0.025 mg/kg/ day as a No Observed Effect Level (NOEL) and a 100-fold uncertainty factor. On reevaluating the 2-year aldrin feeding study in rats, the Agency now considers 0.025 mg/kg/day, the lowest dose tested, to be an LEL rather than an NOEL because of the occurrence of CHIRL.

A preliminary risk assessment for non-oncogenic liver effects has been conducted based on the current PADI for aldrin and human exposure data from an interim report on the first 90 days of a year-long indoor air monitoring study required from the registrant of aldrin through a special data call-in issued by EPA in February 1984. As previously noted, the final results from the completed monitoring study are scheduled for submission to EPA in June 1987.

The pilot phase of this study, carried out in Indianapolis, Indiana, involved treatment of 12 houses, each of crawl-space and basement construction, with Aldrin 4 EC termiticide. Prior to this study, it was believed that aldrin air levels would peak shortly after treatment, and then decline. However, the 90-day pilot results of this study indicate that average air concentrations of aldrin in living rooms and kitchens in both types of structures actually increased slightly between days 28 and 90. The highest aldrin ambient air levels were found in the basement.

Using the results of this report, EPA has evaluated three exposure scenarios, which vary in terms of the level of human activity and amounts of time spent in various parts of the home. As described below, Scenario 1 is considered to represent a reasonably average situation for a working adult, in which the resident is assumed to spend 9 hours outside the home each day, including weekends. By comparison, Scenarios 2 and 3 represent "worst-case" exposure profiles in that the resident is assumed to spend 24 hours per day in the basement or on the first floor of a basement-construction home. Each of these scenarios is necessarily hypothetical, since the life patterns of individuals vary widely, and EPA does not have data on activity patterns and amounts of time spent at home by private individuals.

Specifically, the following assumptions were adopted for each scenario:

- Scenario 1:

  -- The resident spends 15 hours per day in the home, 10 at rest and 5 performing light work, and approximately 80% of this time is spent in areas that can be represented by the mean of the concentrations found in the kitchen and the living room. The remaining time (20%) is spent in the basement.

  -- An average individual has respiratory volumes of 0.44 m^3/hour while at rest, and 1.7 m^3/hour while doing light work.

- Scenario 2:

  -- The resident (an invalid, for example) spends 24 hours per day in the home, virtually all of this time at rest, with a respiratory volume 0.44 m^3/hour.

  -- All of this time is spent on the first floor of a basement-construction home.

- Scenario 3:

  -- As in scenario 2, the resident spends 24 hours per day in the home, virtually all of this time at rest, with a respiratory volume of 0.44 m^3/hour.

  -- All of this time is spent on the basement level.

In addition, certain basic assumptions were made in each instance:

- Aldrin concentrations remain constant at the mean levels achieved 90 days after treatment. Since aldrin air levels actually increased slightly between days 28 and 90 in the pilot monitoring study, there is no justification at this time for assuming that air concentration levels decline after day 90.

- An average individual weighs 60 kg

- Aldrin is totally absorbed in the lung.

Based on mean aldrin ambient air levels at 90 days after treatment, extrapolated to lifetime exposure, the Agency has calculated estimated annual human exposures of 55, 35, and 73 micrograms (ug)/kg/year (daily exposures of 1.51×10^{-4}, 9.6×10^{-5}, and 2.05×10^{-4} mg/kg/day) for Scenarios 1, 2, and 3, respectively. When these estimated exposures are compared to the PADI for aldrin of 3×10^{-5}, the resulting risk estimates for chronic liver effects equate to 500%, 320%, and 680% of the PADI for Scenarios 1, 2, and 3, respectively. Because these preliminarily estimated risks substantially exceed the PADI for aldrin, the Agency is concerned that indoor air exposure to aldrin may pose a significant health risk.

4. Chronic Toxicity: Oncogenicity. During the aldrin/dieldrin suspension and cancellation proceedings, which resulted in the suspension and cancellation of most uses of aldrin and dieldrin, the existing data concerning the oncogenicity of both compounds were subject to intensive evaluation, and the following conclusions were drawn, as stated in the formal opinion issued by the EPA Administrator on the suspension decision:

> "The evidence is conclusive that Aldrin-Dieldrin is carcinogenic in mice. It has produced statistically significant compound-related benign and malignant tumors in the livers of five different strains of mice. It also significantly increases the incidence of lung tumors. This evidence of carcinogenicity is supported by additional, though not definitive, evidence that Aldrin-Dieldrin has increased the incidence of tumors in rats."

An updated assessment of the carcinogenic risks of aldrin and dieldrin has been conducted by EPA's Carcinogen Assessment Group (CAG) in accordance with the Agency's 1984 Proposed Guidelines for Carcinogen Risk Assessment (49 FR 42694; November 23, 1984). Based on this assessment (GS0172-001), aldrin has been classified as a Group B_2 (i.e, probable human) carcinogen, with a cancer potency estimate (Q^{-1*}) of 16 mg/kg body weight/day.

These guidelines describe the general framework to be used in developing an analysis of carcinogenic risk with regard to assessing the weight of evidence of carcinogenicity from human and animal studies. Based on the weight-of-evidence analysis of available data, chemicals are categorized with regard to their potential human carcinogenicity. Under EPA's classification system, Group A, "Human Carcinogen," is reserved for those chemicals for which there is sufficient evidence of carcinogenicity from human epidemiological studies. Group B, "Probable Human Carcinogen," is divided into subgroups 1 and 2. Group B_1 requires some human epidemiological evidence. Since existing epidemiological studies of aldrin provide inadequate evidence for carcinogenicity due to methodological and data limitations, EPA does not have reason to classify aldrin as Group A or B_1.

Under the carcinogen risk assessment guidelines, chemicals are categorized as Group B_2 carcinogens if there is "sufficient evidence" of the chemical's carcinogenicity from animal studies. By comparison, Group C ("Possible Human Carcinogens") chemicals are so classified if there is "limited evidence" from animal studies. There is also a Group D ("Not Classified") and a Group E that is reserved for chemicals shown to be noncarcinogenic in animal and/or human studies.

In classifying aldrin as a Group B_2 carcinogen, the Agency considered all currently available data in both mice and rats. In mice, three long-term carcinogenesis bioassays of aldrin independently conducted by investigators affiliated with the National Cancer Institute (NCI 1978a) and the Food and Drug Administration (Davis and Fitzhugh, 1962; and Davis, 1965), are considered adequate for risk assessment by current scientific standards. In these studies, aldrin was found to produce significant tumor responses in three different strains of mice (C_3H, CF_1, and $B6C3F_1$) in both males and females at both medium and high doses, with a dose-related increase in the proportion of tumors that were malignant. In rats, the available data from seven existing carcinogenicity bioassays are considered inadequate and inconclusive, and a well-designed study in rats is needed to determine the carcinogenic potential of aldrin in this species. However, the available evidence in mice is considered sufficient laboratory evidence to warrant the classification of aldrin as a Group B_2, probable human carcinogen. Further support for this classification comes from the available evidence on the carcinogenicity of dieldrin, the metabolite and epoxidation product of aldrin, and the induction of tumors by other chemicals such as chlordane, chlorendic acid, and heptachlor, which are structurally related to aldrin.[2]

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[2] Dieldrin has also been classified as a Group B_2 (probable human) carcinogen, with a cancer potency estimate (Q^{-1*}) of 20 mg/kg/day. Dieldrin has produced liver carcinomas in multiple strains of mice, with metastasis to the lungs in many instances. Chlordane, heptachlor, and chlorendic acid have produced liver tumors in mice, and chlorendic acid has also produced liver tumors in rats.

Using a cancer potency estimate (Q_1*) for aldrin of 16 mg/kg body weight/day, the Agency has estimated the incremental cancer risks associated with indoor air exposure estimates, based on preliminary data from the ongoing aldrin air monitoring study, of 55, 35, and 73 ug/kg/year. For these three exposure scenarios, the estimated increased cancer risks are 2.4×10^{-3}, 1.5×10^{-3}, and 3.3×10^{-3}, respectively, raising concerns that the termiticide use of aldrin may be posing significant cancer risks to occupants of treated structures.

5. Mutagenicity Studies. A total of 21 mutagenicity studies, some of which were submitted to the Agency in response the the February, 1984 Data Call-In Notice, were reviewed under this Standard. Of these, only two studies -- one, an assay for chromosomal effects and, the other, an unscheduled DNA synthesis (UDS) assay in rat hepatocytes *in vitro* -- were found to be acceptable. Results of the assay for unscheduled DNA synthesis in primary rat hepatocyte cultures (00109564) do not indicate a potential for aldrin to induce primary damage in mammalian cells. However, additional data are needed to confirm this finding, since presumptively positive findings have been reported in other mammalian test systems. Aldrin was negative in a dominant lethal assay of male ICR Swiss mice (00123771). Collectively, the data on file indicate that neither aldrin nor its metabolic degradate dieldrin, possess mutagenic activities in bacteria (GS0172-004). In addition, the data indicate that in eukaryotes, aldrin/dieldrin may act as a promotor rather than an initiator of cancer, though additional testing in mammalian cell systems is necessary to affirm this apparent absence of potential for direct genotoxic activity (GS0172-004). The Agency is requesting the following studies to assess the mutagenic potential of aldrin: mammalian cell gene mutation assays; somatic cell cytogenetic assays; repair in mammalian cell systems; adequately controlled promotion assays; mammalian cell transformation in systems with an established data base; assays for mitotic spindle effects; and assays which can distinguish effects on replicative DNA synthesis from UDS.

6. Metabolism Studies. There are adequate metabolism studies for aldrin. In a study where aldrin was administered to rats by gavage for three months, aldrin was excreted primarily in the feces (00151879). By twelve weeks after the last dose, 99.5 % of all C^{14} administered had been excreted. The fecal and urinary radioactivity consisted of relatively minor amounts of unidentified polar metabolites. In another study in which dogs were dosed orally with gelatin capsules of aldrin at 0.6 mg/kg for 10 months with a 12-month recovery period, no effects on plasma or serum alieterase activities were seen and concentrations of aldrin in blood, fat, and tissues were insignificant. Administration of aldrin resulted in increased concentration of dieldrin in fat and liver and after 10 months reached about 70 and 20 ppm, respectively. When aldrin administration was discontinued, dieldrin levels gradually decreased and dropped to 25 and 6 ppm, respectively, by month 12 (00151872).

7. Teratology and Reproduction. The available reproductive and teratology data are considered supplementary; therefore, data gaps exist in both these areas of toxicity testing. In a supplementary study using hamsters and mice, teratogenic effects were reported at doses purported to be one-half the LD_{50} values (GS0172-001). The teratogenic effects reported were anomalies such as an open eye, cleft palate, and webbed feet, and an increase in fetal deaths as compared to controls. In a multi-generation reproduction study using mice, reduced litter sizes occurred at birth at 10 ppm and above, and it was concluded that at 3 ppm a threshhold NOEL was attained based upon equivocal effects of reduced weanling weights (0090888). In a rat multi-generation study, it was found that only doses above 2.5 ppm in the diet produced significant pregnancy rate reductions, increased losses of litters, and increased mortality in offspring as late as 5 days after delivery (00083074).

8. Applicator Exposure. Because data are not available to characterize applicator exposure, EPA is unable to assess the risks posed to pesticide applicators as a result of dermal and respiratory exposures to aldrin during the termiticide application process. In order to evaluate the risks of occupational exposure to aldrin, the Agency is requiring the submission of appropriate dermal and respiratory data from applicator exposure monitoring studies.

C. ENVIRONMENTAL PROFILE

1. **Ecological Effects**. Additional ecological effects data are not required at this time. Existing data are adequate to show that aldrin is potentially very highly toxic to both warm-water and cold-water fish species. The results of acute warm-water fish studies show LC$_{50}$ values ranging from 5 parts per billion (ppb) for largemouth bass to 53 ppb for channel catfish (00003503). In cold water fish, the values range from 2.6 ppb for rainbow trout to 8.2 ppb for chinook salmon (00003503). Aldrin is also very highly toxic to freshwater invertebrates on an acute basis. The 48-hour EC$_{50}$[3] values range from 18 ppb in a species of seed shrimp to 32 ppb in a species of water flea (00003503).

   Technical aldrin is also potentially very highly toxic to birds. The acute oral LD$_{50}$ ranges from 6.59 mg/kg in the bobwhite quail to 520 mg/kg in mallard ducks (00111910). Dietary studies indicate that technical aldrin is very highly toxic to birds on a subacute dietary basis. The subacute dietary LC$_{50}$ ranges from 34 ppm in the Japanese quail to 155 ppm in the mallard duck (00022923).

   Besides its inherent toxicity, aldrin is highly lipophilic and may bioaccumulate in adipose tissue. This propensity to bioaccumulate could cause aldrin to produce secondary chronic effects in exposed organisms. If the results of environmental fate data and/or monitoring data being required to determine whether the termiticidal use of aldrin may be contaminating surface waters should raise concerns about potential aldrin exposure to fish or fresh-water invertebrates, special monitoring of aquatic sites and chronic fish and wildlife studies may be required.

2. **Endangered Species**. EPA does not have reason to believe that the termiticide use of aldrin threatens any endangered species. The Agency is aware of an incident where lethal concentrations of dieldrin were found in the brains of dead gray bats (myotis grisescens) collected in 1976-77 beneath a maternity roost in a Missouri cave. However, the source of these residues was reported to be the previously legal use of the parent compound aldrin, which had been applied to cornfields for cutworm control. Based on available information, the termiticide use of aldrin according to label directions is not expected to result in exposures that would jeopardize the gray bat or other endangered species.

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[3] Environmental Concentration

3. Environmental Fate. The Agency is unable to fully assess the environmental fate of aldrin, because acceptable data are lacking. However, available, supplementary data do indicate general trends of aldrin behavior in the environment. Aldrin degrades readily to dieldrin, which is persistent in the environment. In column-leaching studies, where aldrin was applied to different soil types and then saturated with water, residues of aldrin remained in the surface few inches of the soil (00103661). Additionally, field studies indicate that residues of aldrin remained in the top half-foot of soil for 1.5 years following application (00103597). Although these reports on leaching and field studies suggest that aldrin/dieldrin would be unlikely to leach to underground aquifers, additional data are necessary to assess the potential for ground-water contamination as a result of the termiticide use of aldrin.

To assess the environmental fate of aldrin in conjunction with its domestic outdoor use pattern, the Agency is requiring the following studies: hydrolysis; aerobic and anaerobic soil metabolism; aerobic aquatic metabolism; leach or adsorption/desorption; terrestrial field dissipation; and photodegradation in water. In addition, a number of data requirements are reserved. Aquatic sediment dissipation data may be required, pending the results of the aerobic aquatic metabolism study. A fish accumulation data are reserved pending the results of the product chemistry requirement for an octanol/water coefficient study. Finally, depending on the results of the indoor air monitoring study now in progress, further testing may be required in this area.

In addition, a special monitoring study is being required to determine the extent of surface water contamination from the termiticide use of aldrin. The purpose of this study is two-fold: (1) to determine whether and to what extent termiticide applications are resulting in residues of aldrin and its metabolite dieldrin in drinking water and in fish for human consumption, and (2) whether fresh-water fish and invertebrates are at risk of being exposed to toxic levels of aldrin and dieldrin as a result of its termiticide use.

This requirement arises from data compiled recently showing significant levels of the termiticide chlordane in fish and bottom sediment in two urban lakes in Iowa, coupled with preliminary data indicating that the source of contamination may be surface water run-off associated with the termiticidal use of chlordane. In 1985, the Iowa Department of Water, Air, and Waste Management sampled urban sources of chlordane, representing a range of potential urban sources. While sampling of storm sewers yielded negative results, trace amounts of chlordane were found at a water treatment plant

(0.18 ppb), a sanitary sewer showed measurable amounts (2.5 and 4.7 ppb), and a significant amount of chlordane was found in a sump pump (180 ppb) (GS0172-002). These preliminary findings on chlordane raise the question whether the termiticide use of aldrin could be contaminating surface water. Chlordane and aldrin, both of which are chlorinated cyclodiene pesticides, have similar physical and chemical properties as well as similar application patterns, and it is reasonable to expect that they may have comparable behavior patterns in the environment.

D. ADDITIONAL CONSIDERATIONS: ALDRIN MISUSE AND MISAPPLICATION

For the purpose of assessing the human health and environmental risks of aldrin, as discussed in this Registration Standard, EPA has assumed the proper use of aldrin as a termiticide in accordance with label directions. However, reports to EPA have indicated a significant incidence of misuse and misapplication of aldrin by professional applicators employing soil injection and trenching methods.

The data indicate that applicators have inadvertently contaminated structures while putting aldrin into prepared injection holes or trenches. These types of incidents underscore the need for applicators to be knowledgeable about building construction elements or anomalies. When applying aldrin by soil treatment methods, it is generally necessary for applicators to take appropriate site-specific precautions. Different types of house construction (i.e., rubble foundations, crawl spaces, etc.) require different methods of treatment as well as techniques to avoid contamination of ventilation systems and other vulnerable areas (electrical conduits, heating pipes or lines, water supplies, etc.).

From an economic standpoint, ignorance or insufficient training regarding these factors can result in significant property damage. Reports indicate that such damage may involve extensive costs, in some instances requiring new ventilation systems, decontamination of drinking water, or replacement of carpeting and wall paneling in the contaminated area. From a health risk standpoint, contaminated air systems may result in unnecessarily high, long-term human exposure to aldrin over and above levels that may be anticipated on the basis of controlled ambient air exposure monitoring. Additionally, the improper use of aldrin has the potential to result in environmental contamination. For these reasons, considered together with the toxic properties of aldrin and its potential to persist and bioaccumulate in the environment in the epoxidized form of dieldrin, EPA is requiring that aldrin be restricted for retail sale to and use by Certified Applicators or persons under their direct supervision, as specifically defined in label provisions prescribed by EPA in this Registration Standard.

E. TOLERANCES AND ACTION LEVELS

Prior to the 1974 suspension and 1975 cancellation of all food and feed uses of aldrin/dieldrin, tolerances for total residues of aldrin and its epoxidation product, dieldrin, resulting in or on raw agricultural commodities from application of aldrin were established as listed in 40 CFR 180.135. As noted in Section I.B of this Registration Standard, tolerances were not revoked concurrently with these cancellations because of the pesticides' slow rate of degradation and their persistence in the environment. However, EPA is now proceeding to revoke these tolerances in accordance with a 1982 agreement among EPA, FDA, and USDA, entitled "Policy Statement on the Revocation of Tolerances for Cancelled Pesticides" (47 FR 42956). This policy statement describes when and how tolerances will be revoked and action levels substituted for certain pesticides for which registered uses have been cancelled, and what factors will be considered in recommending action levels for pesticide residues occurring in food and animal feed commodities as a result of environmental contamination.

The revocation of tolerances supporting previous agricultural uses of aldrin, and EPA's recommendations concerning action levels to replace these tolerances, is independent of this Registration Standard, and is being completed through formal rulemaking. The proposed rule to revoke all tolerances for residues of aldrin and dieldrin under the Federal Food, Drug, and Cosmetic Act (FFDCA) was published March 13, 1985 (50 FR 10080) and public comment was invited. The final rule effecting the revocation of aldrin/dieldrin tolerances is scheduled for publication in the Federal Register in early 1987.

In addition to action levels to replace existing tolerances, EPA is recommending that existing action levels be retained without modification, with the exception of melons. The Agency is recommending that the existing 0.15 ppm action level for melons be lowered to 0.10 ppm. Other existing action levels for aldrin/dieldrin range from 0.03 ppm (hay and other animal feed, and eggs) to 0.3 ppm (milk and dairy products, fats and oils, and fish and shellfish). However, when additional data on current residue levels and fish consumption patterns are collected and analyzed by the Agency, EPA will reassess the present 0.3 ppm action level for fish and shellfish.

IV. REGULATORY POSITION AND RATIONALE

A. REGULATORY POSITIONS AND RATIONALES

Based on review and evaluation of all available data on aldrin, the Agency has made the following determinations. Refer to Sections IV.D. for specific language for label revisions.

1. EPA is currently evaluating the potential human health risks of (1) non-oncogenic chronic liver effects, and (2) oncogenic effects to determine whether additional regulatory action on aldrin may be warranted.

   Rationale: Based on preliminary 90-day mean exposure data from an ongoing, year-long indoor air monitoring study, the risk of liver effects from exposure to ambient air levels of aldrin in treated buldings has been roughly estimated to exceed EPA's Provisional Acceptable Daily Intake (PADI) level for aldrin by three- to seven-fold, depending on the exposure scenario. EPA will also be considering the aforementioned monitoring data together with the evidence on the oncogenicity of aldrin to determine whether human exposure to aldrin may be posing an oncogenic health risk of regulatory concern.

2. In order to meet the statutory standard for continued registration, the Agency has determined that the retail sale and use of all end-use products containing aldrin must be restricted to Certified Applicators or persons under their direct supervision, as specifically defined in the "Restricted Use Pesticide" label provision prescribed by EPA in Section IV.D. of this Registration Standard. As this label provision states, direct supervision of a Certified Applicator means one of two options regarding the use of aldrin products:

   (a) the actual physical presence of the Certified Applicator at the application site during application, or (b) if the Certified Applicator is not physically present at the site, each uncertified applicator must have completed a State approved training course in termiticide application meeting minimal EPA training requirements and be registered in the State in which the applicator is working after a determinatin by the State of the individual's competence.

If States elect to implement the second option provided on the label, then specific, minimum training and registration criteria set forth by EPA must be adopted and followed by the State.

Training may be conducted by industry or other groups provided minimum EPA and State training standards are met. Technicians will not be considered competent until the State has determined that they are competent. Any necessary enabling State legislation and/or regulations will have to be in place before EPA will approve a State program. Before States may exercise this option, a description of their program, including training requirements, approach for determining competence, and registration process must be submitted to and approved by EPA under guidance established by the Agency's Pesticide Certification and Training Office. States may choose to adopt measures more restrictive than those set forth in this Registration Standard.

A State desiring to establish a registration program for termiticide technicians must present to the Agency for approval a program and plan consisting of at least the following elements:

- Training to include basic information on:

  a. Application equipment, rates of application, and mixing, loading, and handling procedures for aldrin products;

  b. Detailed information on construction elements of the structures likely to be encountered when applying aldrin and the appropriate and proper application methods for each construction element;

  c. Operation, care, and maintenance of application equipment and protective equipment and apparel;

  d. Comprehension of label information and restrictions;

  e. Environmental and human health consequences of termiticide misuse including the acute and chronic health hazards of aldrin, potential impact on water supplies, and potential impacts on the environment and treated structures;

  f. Techniques for decontamination, if possible of structures should an accident or misapplication occur;

  g. Safety in storage and disposal of aldrin, aldrin product containers, unused aldrin solution, and contaminated protective equipment and clothing;

h. Emergency procedures, should an accident occur, for the protection of the applicator and the occupants of the treated structure, and warning signs of misapplication that would be useful to communicate to the occupants.

Training developed by industry or others in support of this second option shall be submitted for review and approval to appropriate State regulatory agencies in States which have a termiticide technician training registration program. Such training materials or programs must include at least the above listed elements plus any other requirements which a State might specify.

- Competence demonstrated by: a process or method whereby the State can determine the person is competent to apply the product by examination or other methods acceptable to EPA.

- Registration by: a system of registration with the State after the applicant has demonstrated to the State a satisfactory level of competence in termiticide application.

Rationale: As stated in 40 CFR 162.11(c)(4), pesticide products may be classified for restricted use if there is evidence that the product "may pose a serious hazard to man or the environment which can reasonably be prevented by classification for restricted use." Data reported to EPA indicate recurring misuse and misapplication of aldrin termiticide products by pest control operators. In view of the potential health hazards associated with exposure to aldrin, the Agency is concerned about long-term and acute exposures which may result from the improper use of aldrin. The Agency is especially concerned about the contamination of air systems in structures improperly treated for termite control, since such contamination may result in unnecessarily high, long-term exposure to aldrin over and above levels that may be anticipated on the basis of controlled ambient air exposure monitoring. In addition, the misuse of aldrin has the potential to result in environmental contamination.

Several States have already restricted the use of aldrin. EPA believes that the incidence of misapplication and misuse of aldrin can be mitigated by restricting the use of all aldrin products to Certified Applicators or persons under their direct supervision, as defined above and in the "Restricted-Use Pesticide" label provision prescribed in Section IV.D. By presenting two options for compliance with the restricted use requirement for aldrin, it is EPA's intent to ensure that aldrin is competently applied: either under the immediate, physical supervision of a responsible Certified Applicator who can direct the implementation of site-specific precautions as appropriate (Option 1); or, if a Certified Applicator is not physically present, each State-registered technician working at the site will have demonstrated competence to safely conduct termiticide applications, following completion of a training course in termiticide application administered by the State in which he or she is working (Option 2).

The two options are intended to offer States some administrative discretion in regulating professional pest control operations under their jurisdiction. At the same time, EPA believes that either option will serve to upgrade competence among users of aldrin. EPA believes that, where a Certified Applicator is not physically present, formally trained technicians are less likely to misuse or misapply aldrin. The minimum training and registration criteria set forth in this Registration Standard for State programs are intended to ensure that all users of aldrin who are not Certified Applicators have demonstrated competence in all aspects of termiticide application ranging from comprehension of the importance of label precautions to practical knowledge of emergency procedures in the event that an accident should occur.

3. In order to meet the statutory standard for continued registration, the Agency has determined that aldrin product labels must be revised to provide specific aldrin disposal procedures.

   Rationale: Aldrin products are acutely hazardous when discarded, and improper disposal of excess pesticide, spray mixture, or rinsate may result in environmental contamination.

4. In order to meet the statutory standard for continued registration, the Agency has determined that aldrin products must bear fish and wildlife toxicity warnings.

   Rationale: Data reviewed by EPA have shown that aldrin is very highly toxic to warm- and cold-water fish species, and to freshwater invertebrates; aldrin is also potentially very highly toxic to birds. It is therefore imperative that effluent containing aldrin not be improperly discharged into surface waters or sewer systems.

5. A special monitoring study is required to evaluate whether and to what extent surface water contamination may be resulting from aldrin's use as a termiticide.

Rationale: Aldrin and its metabolite dieldrin are persistent in the environment and can bioaccumulate in fish and fresh-water invertebrates. Human dietary exposure to aldrin may occur through consumption of contaminated drinking water and fish. In addition, aldrin is potentially very highly toxic to fish and freshwater invertebrates. The physical and chemical properties of aldrin are similar to the properties of chlordane, a cyclodiene termiticide which has been found at significant levels in urban lakes in Iowa; preliminary evidence indicates that the source of contamination may be the termiticidal use of chlordane. Both chemicals also have similar application patterns, and it is reasonable to expect that they may have comparable behavior patterns in the environment. The Agency is therefore requiring a study, in which sump pump, drainage tiles and sanitary sewer water, draining from home foundations known to have been properly treated with aldrin, are sampled for aldrin residues. Based on the results of this study, additional regulatory action may be warranted.

6. Special product-specific subacute inhalation testing is required to evaluate the respiratory hazards to humans in structures treated with termiticide products containing aldrin.

Rationale: The Agency has received reports from individuals complaining of upper respiratory problems associated with termiticidal application of aldrin. To investigate the extent of the problem, the Agency is requiring testing to determine the potential of aldrin itself, the formulation solvent(s), or the aldrin/solvent combination to cause irritation of mucous membranes. Pending the results of this testing, additional regulatory measures may be appropriate.

7. The Agency is requiring the submission of applicator exposure data from dermal and respiratory routes of exposure.

Rationale: Additional data are needed to determine whether exposure to applicators during termiticide application may be posing significant health risks. Registrants are referred to Subdivision U of the Pesticide Assessment Guidelines for acceptable exposure monitoring methodology. The Guideline document is publicly available through the National Technical Information Service (NTIS), Springfield, Virginia 22161 (telephone: 703-487-4650). Registrants must submit appropriate protocols for these exposure studies within 90 days.

7(a). In order to meet the statutory standard for continued registration the Agency has determined that the existing use directions under the current termiticide LIP for aldrin product labels must be clarified in order to further minimize human exposure and avoid contamination of the environment.

Rationale: Under the current termiticide LIP questions have been raised regarding existing use directions pertaining to soil treatment. Information indicates that certain treatment procedures need clarification to accomodate technical and safety aspects of termite control and minimize exposure to homeowners and applicators. Such revisions and precautions make the treatment instructions more clear, minimize misapplication and ensure compliance.

8. In order to meet the statutory standard for continued registration the Agency has determined that aldrin product labels must contain a prohibition against application to plenum houses (houses where the crawlspace beneath the building is used to circulate heated or cooled air without ductwork).

Rationale: This restriction is necessary to guard against potentially high levels of exposure. Information indicates that application to these houses can result in very high indoor air levels.

9. While data gaps are being filled, currently registered manufacturing use products (MPs) and end-use products (EPs) containing aldrin as the sole active ingredient may be sold, distributed, formulated, and used, subject to the terms and conditions specified in this Standard. Registrants must provide or agree to develop additional data, as specified in the Data Appendices, in order to maintain existing registrations.

Rationale: Under FIFRA, the Agency does not normally cancel or withhold registration simply because data are missing or are inadequate (see FIFRA sec. 3(c)(2)(B) and 3(c)(7). Issuance of this Standard provides a mechanism for identifying data needs. These data will be reviewed and evaluated, after which the Agency will determine if additional regulatory changes are necessary.

10. The Agency has identified certain data requirements that will receive priority review when received.

Rationale: Certain data are essential to the Agency's assessment of this pesticide and its uses and/or may trigger the need for further studies which should be initiated as soon as possible. The following studies have been identified to receive priority review as soon as they are received by the Agency:

§158.135 Toxicology

83-2 Rat Oncogenicity Study
83-3 Teratogenicity- Rat and Rabbit
83-4 Reproduction- Rat
84-2 Gene Mutation and Structural Chromosomal Aberration
84-4 Other Genotroxic Effects
Special Test- Guinea Pig Inhalation Study

§158.130 Environmental Fate

161-1	Hydrolysis
161-2	Photodegradation in Water
162-1	Aerobic Soil Metabolism
162-2	Anaerobic Soil Metabolism
162-4	Aerobic Aquatic Metabolism
163-1	Leaching and Adsorption/Desorption
164-1	Soil Dissipation Study

Water Monitoring Study
Applicator Exposure Study
Indoor Air Monitoring Study

B. CRITERIA FOR REGISTRATION

This Standard covers both manufacturing-use products (MPs) and end-use products (EPs) containing aldrin[4]. Registrants of aldrin products must comply with all terms and conditions described in this section, including submission of an up-to-date Confidential Statement of Formula, submission of revised labeling, commitment to fill data gaps on the schedule specified by the Agency and, when applicable, offer to pay compensation as required by 3(c)(1)(D) and 3(c)(2)(D) of the FIFRA.

C. ACCEPTABLE RANGES AND LIMITS

1. Product Composition Standard - Each product proposed for registration or reregistration must be fully described with an appropriate certification of limits, stating maximum and minimum amounts of the active and intentionally added inert ingredients which will be present in the product. The active ingredient in any new product must be substantially similar to that in currently registered aldrin products.

2. Acute Toxicity Limits - The Agency will consider registration of any product in any Toxicity Category provided the product labeling bears appropriate precautionary statements.

3. Use Patterns - Manufacturing-use products containing aldrin must be labeled for formulation into end-use products only for termite control. The EPA Compendium of Acceptable Uses, Appendix III, lists the approved application rates and methods of application.

D. REQUIRED LABELING

All manufacturing-use products (including formulation intermediates) and end-use products must bear appropriate labeling as specified in 40 CFR 162.10, PR Notices 83-2 and 83-3, and as indicated in this Registration Standard (as appropriate).

End-use or manufacturing-use product containing aldrin may not be released for shipment by a registrant or producer of that product 12 months after the registrant's or producer's receipt of this Registration Standard, unless the product bears an EPA-approved amended label which complies with this Registration Standard.

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[4] The Agency considers all currently registered end-use products containing aldrin to be sole active ingredient formulations. The Agency does not consider solvents or diluents to be insecticidal and therefore, must be declared as inert ingredients.

End-use or manufacturing-use product containing aldrin may not be distributed, sold, offered for sale, held for sale, shipped, delivered for shipment, or received and (having been so received) delivered or offered to be delivered by any person 24 months after issuance of this Registration Standard, unless the product bears an EPA-approved amended label which complies with this Registration Standard.

1. All Products - All products must bear appropriate labeling as specified in 40 CFR 162.10. Appendix II contains information on labeling requirements. The following pesticide disposal statement must appear on all labels:

> "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

2. Manufacturing-use Products - All manufacturing-use products must bear the following statements:

> "For formulation into end-use insecticide products intended only for termiticide use."

> "This pesticide is toxic to fish and wildlife. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."

> "The use of this product may be hazardous to your health. This product contains aldrin, which has been determined to cause cancer and adverse liver effects in laboratory animals."

> "Mixer/loaders must wear goggles or a face shield, chemical-resistant apron, long-sleeved shirt and long pants, or coveralls, and unlined, mid-forearm to elbow length chemical-resistant gloves when mixing, loading, or otherwise handling concentrate."

"Any article of clothing worn while applying pesticide must be cleaned before re-use. Clothing should be laundered separately from household articles. Clothing that has been drenched or has otherwise absorbed concentrated pesticide must be disposed of in a sanitary landfill, incinerated, or burned if allowed by State or local authorities."

3. End-use Products - Labels for all end-use products must bear the following statements:

"RESTRICTED-USE PESTICIDE

The use of this product may be hazardous to your health. This product contains aldrin, which has been determined to cause cancer and adverse liver effects in laboratory animals. This pesticide persists in the environment and bioaccumulates in living organisms. Risks can be reduced by closely following all use directions and precautions, and by wearing the protective clothing specified elsewhere on this label. Treated buildings may be contaminated, resulting in hazards to the health of occupants if this product is not properly applied and used only for the purpose stated on the label.

For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification. For the purposes of this product, direct supervision of a Certified Applicator means either: 1) the actual physical presence of the Certified Applicator at the application site during application, or 2) if the Certified Applicator is not physically present at the site, each uncertified applicator acting under instructions and control of the Certified Applicator who is available if and when needed, must have completed a State approved training course which meets EPA minimal requirements in termiticide application and must be registered for termiticide application in the State in which the uncertified applicator is working."

"This pesticide is toxic to fish and wildlife. Do not apply directly to water. Do not contaminate water by cleaning of equipment or disposal of waste."

"Applicators must wear water-resistant hat, lightweight protective suit or coveralls, unlined chemical-resistant gloves (natural rubber, neoprene, or polyethylene), and unlined lightweight boots. MSHA/OSHA approved respirators are required for applications in enclosed areas such as crawl spaces. Mixer/loaders must wear goggles or a face shield, chemical-resistant apron, long-sleeved shirt and long pants, or coveralls, and unlined, mid-forearm to elbow length chemical-resistant gloves when mixing, loading, or otherwise handling the concentrate."

" Any article of clothing worn while applying product must be cleaned before re-use. Clothing should be laundered separately from household articles. Clothing that has been drenched or has otherwise absorbed concentrated pesticide must be disposed of in a sanitary landfill, incinerated, or burned if allowed by State or local authorities."

"Do not apply aldrin in or around poultry houses, barns, silos, milk houses, or other structures or enclosures where livestock or poultry is held, or where food/feed is stored, prepared or processed."

"Do not apply aldrin to plenum houses (houses where the crawlspace beneath the building is used to circulate heated or cooled air without ductwork)."

4. Labels for all end-use products bearing directions for subterranean termite control must be revised to include the following (Note: each revision/change to the current LIP use directions are high;ighted for easy reference):

GENERAL INFORMATION ON THE USE OF THIS PRODUCT

Chemicals for soil treatment are used to establish a barrier against termites. The chemical emulsion must be adequately dispersed in the soil to provide a barrier between the wood in the structure and the termite colonies in the soil.

It is necessary for the effective use of this product that the service technician be familiar with current control practices including trenching, rodding, subslab injection and low-pressure applications. These techniques must be correctly employed to prevent or control infestations by subterranean termites such as Reticulitermes, Zootermopsis, Heterotermes, and Coptotermes. Choice of appropriate procedures should include consideration of such variable factors as the design of the structure, existence of air circulation in subfloor crawlspace, watertable, soil type, soil compaction, grade conditions, and the location and type of domestic water supplies *and drainage systems.* The biology and behavior of the termite species involved are important factors to be known, as well as suspected location of the colony and severity of the infestation within the structure to be protected.

All nonessential wood and cellulose-containing materials, including scrap wood and form boards, should be removed from around foundation walls, crawlspaces, and porches. *Effective termite control also includes elimination of termite access to moisture by recommending repair of faulty construction, grade, and/or plumbing.*

For advice concerning current control practices with relation to the specific local conditions, consult resources in structural pest control and the State regulatory agency.

SUBTERRANEAN TERMITE CONTROL
DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. *This product may not be used against any pests not named on the label. Apply only to establish subsurface termite control barriers specified on product labeling.*

Contamination of public and private water supplies must be avoided by following these precautions: Use antibackflow equipment or procedures to prevent siphonage of pesticide back into water supplies. Do not treat soil beneath structures that contain cisterns or wells. Do not treat soil that is water saturated or frozen. Consult State and local specifications for recommended distances of treatment areas from wells. *If no State or local government recommendations are available, refer to Federal Housing Administration specifications for further guidance.*

PRECONSTRUCTION SUBTERRANEAN TERMITE TREATMENT

Effective preconstruction subterranean termite control requires the establishment of an unbroken vertical and/or horizontal chemical barrier between wood in the structure and the potential or existing termite colonies in the soil. To meet FHA termite-proofing requirements, follow the latest edition of the Housing and Urban Development (HUD) Minimum Property Standards.

Use a ____ water emulsion for subterranean termites. Mix ____ gallon of (product name) in ____ gallons of water to produce a water emulsion.

Do not apply to any area intended as a plenum airspace. Check with the builder or contractor to determine if the design of the structure includes a plenum airspace.

HORIZONTAL BARRIERS

Before footings are poured, horizontal barriers may be established in footing trenches. Then, after interior grading is completed and prior to the pouring of concrete slabs, horizontal barriers may be established on soil that will be covered by floors, entrance platforms, or porches, and in other critical areas that will be covered by construction. To produce a horizontal barrier, apply the emulsion at the rate of 1 gallon per 10 square feet to fill dirt. If fill is washed gravel or other coarse material, apply at 1 1/2 gallons per 10 square feet.

- *It is important that the emulsion reaches the soil.*
- *Applications shall be made with low pressure (less than 50 psi at the nozzle) using a coarse-spray nozzle when establishing horizontal barriers.*
- *If concrete slabs cannot be poured over soil the same day it has been treated, a waterproof cover such as polyethylene sheeting should be placed over the soil to prevent erosion. This is not necessary if foundation walls have been installed around the treated soil.*

VERTICAL BARRIERS

After the foundation walls have been poured or built, vertical barriers may be established around the perimeters of floating or supported slabs, around utilities penetrating the slab, and in other critical areas. After the final exterior grading is completed, vertical barriers may be created in back-filled soil *against foundation walls. To produce a vertical barrier, apply the emulsion at the rate of 4 gallons per 10 linear feet per foot of depth from grade to the top of the footing.*

- Rodding and/or trenching applications should not be made below the top of the footing *except when the footing is exposed at or above grade. Special care should be taken to avoid soil washout around the footing.*
- Trenches need not be wider than 6 inches.
- When rodding, it is important that emulsion reaches the footing. Rodholes should be spaced to provide a continuous barrier.
- Emulsion should be mixed with the soil as it is being replaced in the trench. Cover treated soil with a layer of untreated soil.

HOLLOW MASONRY UNITS OF FOUNDATION WALLS

In preconstruction situations in which application is not made to soil prior to pouring the footing, treatment may be made through masonry voids to establish a continuous chemical barrier at the top of the footing. Apply at the rate of 2 gallons of emulsion per 10 linear feet of footing.

Do not treat in this manner through voids in walls constructed on interior slabs such as basement floors.

CRAWLSPACES

For crawlspaces, vertical barriers may be established using a rate of 4 gallons of emulsion per 10 linear feet per foot of depth from grade to the top of the footing. Application may be made by rodding and/or trenching to the footing. *If the footing is exposed at or above grade, application should be made with special care to avoid washout around the footing. Treatment should include both sides of foundation and around all piers and pipes extending from the soil. To avoid volatilization into air within the structure, do not make an overall broadcast application to areas intended to be crawlspaces; apply by rodding and/or trenching.*

- Rodholes should be spaced to provide a continuous chemical barrier.
- Trenches need not be wider than 6 inches nor below the footing. The emulsion should be mixed with the soil as it is being replaced in the trench. Cover the treated soil

with a layer of untreated soil. *Moisture barriers such as polyethylene sheeting may be used in addition to the untreated soils.*

MONOLITHIC SLABS

In the case of a single-pour monolithic slab that does not have a separate foundation or footing, an overall horizontal barrier should be created before the concrete is poured using a rate of 1 gallon of emulsion per 10 square feet. If fill is washed gravel or other coarse material, apply at the rate of 1 1/2 gallons per 10 square feet. Critical areas beneath the slab such as utility pipe entries may be treated at the rate of 4 gallons per 10 linear feet around the pipe.

Exterior vertical barriers should be created after the concrete has been poured and final grade established. Apply the emulsion at the rate of 4 gallons per 10 linear feet per foot of depth to the bottom of the concrete.

POSTCONSTRUCTION TREATMENTS

Use a ____ water emulsion for subterranean termites. Mix ____ gallon of (product name) in ____ gallons of water to produce a ____ water emulsion.

Postconstruction applications may be made by injection, rodding and/or trenching with pressures less than 25 psi at the nozzle. *To avoid volatilization into the air within the structure, do not make an overall broadcast application of this product in a crawl-space. Rodholes or trenches should not extend below the footing because of the possibility of soil washout by the emulsion.*

Do not apply this product to the soil beneath a plenum airspace.

Do not apply emulsion until location of heat or air conditioning ducts, vents, water and sewer lines, and electrical conduits are known and identified. *Do not apply this product to soil beneath slabs with subslab or intraslab ducting until ducts are permanently plugged.* **Surface application is prohibited. (italics)**

CONCRETE SLABS

Vertical barriers may be established by subslab injection inside and rodding and/or trenching outside at the rate of 4 gallons of emulsion per 10 linear feet. Injectors should not extend beyond the tops of the footings.

Treat along the outside of the foundation and where necessary just beneath the slab on the inside of foundation walls. Treatment may also be required just beneath the slab along both sides of interior footing-supported walls, one side of interior partitions, and along cracks and expansion joints. *Horizontal barriers may be established where necessary by long rodding or by a grid pattern injection using a rate of 1 to 1 1/2 gallons of emulsion per 10 square feet depending on fill type and condition.*

- Drill holes in the slab about 12 to 36 inches apart to provide a continuous chemical barrier.
- Where necessary, drill through the foundation walls from the outside and *inject* the emulsion just beneath the slab either along the inside of the foundation or along cracks, expansion joints, and other critical areas.
- For shallow foundations 1 foot or less, dig a narrow trench approximately 6 inches wide along the outside of the foundation walls. Do not *trench* below the bottom of the foundation. The emulsion should be applied to the trench and the soil at 4 gallons per 10 linear feet as the soil is replaced in the trench. Cover the treated soil with a layer of untreated soil.
- For foundations deeper than 1 foot follow rates for basements.

HOLLOW MASONRY UNITS OF FOUNDATION WALLS

Treatment may be made through masonry voids to establish a continuous chemical barrier at the top of the footing. Apply at the rate of 2 gallons of emulsion per 10 linear feet of footing. Where this treatment is necessary, access holes must be drilled below the sill plate and should be through a lower mortar joint. Before treatment through basement walls, seal the interior wall and floor expansion joint with mortar, caulk, waterproofing material, or similar impervious sealant. Also, seal openings at the top of the foundation wall. Do not treat in this manner through voids in walls constructed on interior slabs such as basement floors.

BASEMENTS

For basements and slab foundations that extend more than 1 foot below grade, vertical barriers may be applied at a rate of 4 gallons of emulsion per 10 linear feet per foot of depth from grade to the top of the footing. Treat the outside of the foundation by trenching and/or rodding. Subslab injection may be necessary along the inside of foundation walls, along cracks, along partitions, around sewer pipes, conduits, and piers, and along both sides of interior footing-supported walls.

CRAWLSPACES

In crawlspaces, vertical barriers may be applied at the rate of 4 gallons of emulsion per 10 linear feet per foot of depth from grade to top of footing. Application may be made by rodding and/or trenching.

Do not apply this product to the soil beneath a plenum airspace.

To avoid volatilization into air within the structure, do not make an overall broadcast application of this product in a crawlspace: apply by rodding and/or trenching. Rodholes or trenches should not extend below the footing. Treat both sides of foundation and around all piers and pipes.

- Rodholes should be spaced to provide a continuous chemical barrier.

- Trenches need not be wider than 6 inches nor below the footing. The emulsion should be mixed with the soil as it is replaced in the trench. Cover the treated soil with a layer of untreated soil. *Moisture barriers such as polyethylene sheeting may be used in addition to the untreated soil.*

- *If it is necessary to make an overall barrier under soil in a crawlspace, this treatment may only be made by injecting the emulsion several inches below the soil surface.*

- *It should be recommended that inadequately ventilated crawlspaces be brought into compliance with FHA Minimum Property Standards specifying 1 square foot of ventilator opening per 150 square feet of crawlspace area.*

EXCAVATION TECHNIQUE

If treatment must be made in difficult situations such as near wells or cisterns, along faulty foundation walls, and around pipes and utility lines which lead downward from the structure, application may be made in the following manner:

- *Trench and remove the soil to be treated onto heavy plastic sheeting or similar liner.*

- *Treat the soil at the rate of 4 gallons of emulsion per 10 linear feet per foot of depth of the trench. Mix the emulsion thoroughly into the soil taking care to prevent liquid from running off the liner.*

- *After the treated soil has dried adquately, replace the soil in the trench and cover with a layer of untreated soil.*

Prior to using this technique near wells or cisterns, consult State, local, or Federal regulatory agencies for information regarding approved treatment practices in your area.

AFTER TREATMENT

Before leaving the job site, securely plug all holes drilled in construction elements of commonly occupied areas of structures, including unfinished basements, enclosed porches, garages, and workshops.

RETREATMENT

Retreatment for subterranean termites should only be made when there is evidence of reinfestation subsequent to the initial treatment, or there has been a disruption of the chemical barrier in the soil due to construction, excavation, landscaping, etc. Retreatment should be made as a spot application to these areas.

Retreatments may be made to critical areas in accordance with the application techniques described above. This application should be made as a spot treatment to these areas. Routine retreatment of the entire premises should be avoided.

V. PRODUCTS SUBJECT TO THIS STANDARD

All products containing one or more of the pesticides identified in Section II.A. are subject to certain requirements for data submission or changes in composition, labeling or packaging of the product. The applicable requirements depend on whether the product is a manufacturing or end use product and whether the pesticide is the sole active ingredient or one of multiple active ingredients.

Products are subject to this Registration Standard as follows:

A. Manufacturing use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV, if they pertain to the manufacturing use product.

2. The data requirements listed in Tables A and B.[2]

3. The labeling requirements specified for manufacturing use products in Section IV.

4. Administrative requirements (application forms, Confidential Statement of Formula, data compensation provisions) associated with reregistration.

B. Manufacturing use products containing this pesticide as one of multiple active ingredients are subject to:

The data requirements listed in Table A and labeling requirements specified for manufacturing use products in Section IV.

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[2] Data requirements are listed in the three Tables in Appendix I of this Registration Standard. The Guide to Tables in that Appendix explains how to read the Tables.

Table A lists generic data requirements applicable to all products containing the pesticide subject to this Registration Standard. Table B lists product-specific data applicable to manufacturing use products. The data in Tables A and B need not be submitted by a producer who is eligible for the formulator's exemption for that active ingredient.

Table C lists product-specific data applicable to end use products. The Agency has decided that, in most cases, it will not require the submission of product-specific data for end use products at this time. Therefore most Registration Standards do not contain a Table C.

C. End use products containing this pesticide as the sole active ingredient* are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV if they pertain to the end use product.

2. If eligible for the formulator's exemption[3], the data requirements listed in Table C.

3. If not eligible for the formulator's exemption, the data requirements listed in Table A and the data requirements listed in Table C.

4. The labeling requirements specified for end use products in Section IV.

* solvents or diluents must be declared as inerts. The Agency does not have data indicating that these solvents are insecticidal.

D. End use products containing this pesticide as one of multiple active ingredients are subject to:

a. If not eligible for the formulator's exemption, the date requirements listed in Tables A and C.

b. If eligible for the formulator's exemption, the data requirements listed in Table C.

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[3] If you purchase from another producer and use as the source of your active ingredient only EPA-registered products, you are eligible for the formulator's exemption for generic data concerning that active ingredient (Table A) and product-specific data for the registered manufacturing use product you purchase (Table B).

Two circumstances nullify this exemption:

1) If you change sources of active ingredient to an unregistered product, formulate your own active ingredient, or acquire your active ingredient from a firm with ownership in common with yours, you individually lose the exemption and become subject to the data requirements in Table A.

2) If no producer subject to the generic data requirements in Table A agrees to submit the required data, all end use producers lose the exemption, and become subject to those Data requirements.

VI. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

This portion of the Registration Standard is a notice issued under the authority of FIFRA sec. 3(c)(2)(B). It refers to the data listed in Table A, which are required to be submitted by registrants to maintain in effect the registration of products containing this active ingredient.[4]

A. What are generic data?

Generic data pertain to the properties or effects of a particular active ingredient. Such data are relevant to an evaluation of all products containing that active ingredient regardless of whether the product contains other ingredients. (unless the product bears labeling that would make the data requirement inapplicable).

Generic data may also be data on a "typical formulation" of a product. "Typical formulation" testing is often required for ecological effects studies and applies to all products having that formulation type. These are classed as generic data, and are contained in Table A.

B. Who must submit generic data?

All current registrants are responsible for submitting generic data in response to a data request under FIFRA sec. 3(c)(2)(B) (DCI Notice). EPA has decided, however, not to require a registrant who qualifies for the formulator's exemption (FIFRA sec. 3(c)(2)(D) and § 152.85) to submit generic data in response to a DCI notice if the registrant who supplies the active ingredient in his product is complying with the data request.

If you are not now eligible for a formulator's exemption, you may qualify for one if you change your source of supply to a registered source that does not share ownership in common with your firm. If you choose to change sources of supply, the Confidential Statement of Formula must identify the new source(s) and you must submit a Formulator's Exemption Statement form.

If you apply for a new registration for products containing this active ingredient after the issuance of this Registration Standard, you will be required to submit or cite generic data relevant to the uses of your product if, at the time the application is submitted, the data have been submitted to the Agency by current registrants. If the required data have not yet been submitted, any new registration will be conditioned upon the new registrant's submission or citation of the required data not later than the date upon which current registrants of similar products are required to provide such data. See FIFRA sec. 3(c)(7)(A). If you thereafter fail to comply with the condition of that registration to provide data, the registration may be cancelled (FIFRA sec. 6(e)).

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[4] Registrations granted after issuance of this Standard will be conditioned upon submission or citation of the data listed in this Registration Standard.

C. What generic data must be submitted?

You may determine which generic data you must submit by consulting Table A. That table lists the generic data needed to evaluate current uses of all products containing this active ingredient, the uses for which such data are required, and the dates by which the data must be submitted to the Agency.

D. How to comply with DCI requirements.

Within 90 days of your receipt of this Registration Standard, you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1, enclosed) for each of your products. On that form you must state which of the following six methods you will use to comply with the DCI requirements:

1. You will submit the data yourself.

2. You have entered into an agreement with one or more registrants to jointly develop (or share in the cost of developing) the data, but will not be submitting the data yourself. If you use this method, you must state who will submit the data on which you will rely. You must also provide EPA with documentary evidence that an agreement has been formed which allows you to rely upon the data to be submitted. Such evidence may be: (1) your letter offering to join in an agreement and the other registrant's acceptance of your offer, (2) a written statement by the parties that an agreement exists, or (3) a written statement by the person who will be submitting the data that you may rely upon its submission. The Agency will also require adequate assurance that the person whom you state will provide the data is taking appropriate steps to secure it. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or a mechanism to resolve the terms.

3. You have attempted to enter into an agreement to jointly develop data, but no other registrant has accepted your offer. You request that EPA not suspend your registration for non-compliance with the DCI. EPA has determined that, as a general policy, it will not suspend the registration of a product when the registrant has in good faith sought and continues to seek to enter into a data development/cost sharing program, but the other registrants developing the data have refused to accept its offer. [If your offer is accepted, you may qualify for Option 2 above by entering into an agreement to supply the data.]

In order to qualify for this method, you must:

1. File with EPA a completed "Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data" (EPA Form 8580-6, enclosed).

2. Provide us with a copy of your offer to the other registrant and proof of the other registrant's receipt of your offer (such as a certified mail receipt). Your offer must, at a minimum, contain the following language or its equivalent:

> [Your company name] offers to share in the burden of producing the data required pursuant to FIFRA sec. 3(c)(2)(B) in the [name of active ingredient] Registration Standard upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii).

The remainder of your offer may not in any way attempt to limit this commitment. If the other registrant to whom your offer is made does not accept your offer, and if the other registrant informs us on a DCI Summary Sheet that he will develop and submit the data required under the DCI, then you may qualify for this option. In order for you to avoid suspension under this method, you may not later withdraw or limit your offer to share in the burden of developing the data. In addition, the other registrant must fulfill its commitment to develop and submit the data.

4. You request a waiver of the data requirement. If you believe that a data requirement does not (or should not) apply to your product or its uses, you must provide EPA with a statement of the reasons why you believe this is so. Your statement must address the specific composition or use factors that lead you to believe that a requirement does not apply. Since the Agency has carefully considered the composition and uses of pesticide products in determining that a data requirement applies, EPA does not anticipate that many waivers will be granted. A request for waiver does not extend the timeframes for developing required data, and if your waiver request is denied, your registration may be suspended if you fail to submit the data.

5. You request that EPA amend your registration by deleting the uses for which the data are needed. You are not required to submit data for uses which are no longer on your label.

6. You request voluntary cancellation of the registration of your product(s) for which the data are needed.

E. Procedures for requesting a change in testing protocol.

If you will generate the required data and plan to use test procedures which deviate from (or are not specified in) either EPA's Pesticide Assessment Guidelines or the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit for EPA approval the protocols you propose to use.

You should submit your protocols before beginning testing and await EPA approval, because the Agency will not ordinarily accept as sufficient studies using unapproved protocols. A request for protocol approval will not extend the timeframe for submission of the data, nor will extensions generally be given to conduct studies due to submittal of inappropriate. protocols.

F. Procedures for requesting extensions of time.

If you think that you will need more time to generate the data than is allowed by EPA's schedule, you may submit a request for an extension of time. Any request for a time extension which is made as an initial response to a section 3(c)(2)(B) request notice must be submitted in writing to the Product Manager listed at the end of this section and must be made before the deadline for response. Once dates have been committed to and EPA has accepted these commitments, any subsequent requests for a time extension must be submitted in writing to the Office of Compliance Monitoring.

EPA will view failure to request an extension before the response deadline as a waiver of any future claim that there was insufficient time to submit the data. While EPA considers your request, you must strive to meet the deadline for submitting the data.

The extension request should state the reasons why you believe that an extension is necessary and the steps you have taken to meet the testing deadline. Time extensions normally will not be granted due to problems with laboratory capacity or adequacy of funding, since the Agency believes that with proper planning these can be overcome. Time extensions may be considered when joint data development is planned, or when the Agency must approve a new or modified protocol before the study can be begun.

A request for an extension does not extend the timeframe for submission of the data. If EPA denies your request for a time extension and you do not submit the data as requested, EPA may begin proceedings to suspend the registrations of your products.

G. Existing stocks provision upon suspension or cancellation.

The Agency has determined that if a registration is suspended for failure to respond to a DCI request under FIFRA sec. 3(c)(2)(B), an existing stocks provision is not consistent with the Act. Accordingly, the Agency does not anticipate granting permission to sell or distribute existing stocks of suspended product except in rare circumstances. If you believe that your product will be suspended or cancelled and that an existing stocks provision should be granted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. The following information must be included in any request for an existing stocks provision:

1. Explanation of why an existing stocks provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale or distribution; and

2. Demonstration that such a provision would be consistent with the provisions of FIFRA.

VII. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Under its DCI authority, EPA has determined that certain product-specific data are required to maintain your registrations in effect. Product-specific data are derived from testing using a specific formulated product, and, unlike generic data, generally support only the registration of that product. All such data must be submitted by the dates specified in this Registration Standard.

If you have a manufacturing use product, these data are listed in Table B. If you have an end use product, the data are listed in Table C. As noted earlier, the Agency has decided that it will not routinely require product-specific data for end use products at this time. Therefore, Table C may not be contained in this Registration Standard; if there is no Table C, you are not required to submit the data at this time.

In order to comply with the product specific data requirements, you must follow the same procedures as for generic data. See Section IV.D, E, F, and G. You should note, however, that product chemistry data are required for every product, and the only acceptable responses are options IV.D.1. (submit data) or IV.D.6.(cancellation of registration).

Failure to comply with the product-specific data requirements for your products will result in suspension of the product's registration.

VIII. REQUIREMENT FOR SUBMISSION OF REVISED LABELING

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the Agency's assessment of the data supporting the product and its uses. General labeling requirements are set out in 40 CFR 162.10 (see Appendix II - LABELING and SUMMARY). In addition, labeling requirements specific to products containing this pesticide are specified in Section IV.D of this Registration Standard. Applications submitted in response to this notice must include draft labeling for Agency review.

If you fail to submit revised labeling as required, which complies with 40 CFR 162.10 and the specific instructions in Section IV.D., EPA may seek to cancel or suspend the registration of your product under FIFRA sec. 6.

IX. INSTRUCTIONS FOR SUBMISSION

A. Manufacturing Use Products (MUPs) containing Aldrin as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division for each product subject to this Registration Standard:

a. The "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1), with appropriate attachments.[5]

b. Confidential Statement of Formula (EPA Form 8570-4), attached separately.

c. Formulator's Exemption Statement, if applicable.

d. Evidence of compliance with data compensation requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR 152.80-152.99.

2. Within 9 months from receipt of this document you must submit to the Product Manager:

a. Two copies of any required product-specific data (See Table B).

b. Five (5) copies of draft labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft label must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

c. Product Specific Data Report.

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[5] If on the Summary Sheet, you commit to develop the data, present arguments that a data requirement is not applicable or should be waived, or submit protocols or modified protocols for Agency review, you must submit a copy of the Summary Sheet (and any supporting information) to the Office of Compliance Monitoring, which will be monitoring the data generated in response to this notice. This submission is in addition to responding to the Product Manager, and should be submitted to the Office of Compliance Monitoring at the address given at the end of this section. (Actual studies are not to be submitted to the Office of Compliance Monitoring.)

3. Within the times set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Product Manager and the Office of Compliance Monitoring of the problem, the reasons for the problem, and your proposed course of action.

B. Manufacturing Use Products containing Aldrin in combination with other active ingredients.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division:

a. FIFRA sec. 3(c)(2)(B) Summary Sheet, with appropriate attachments[5] (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4), attached separately.

c. Formulator's Exemption Statement, if applicable.

2. Within 9 months from receipt of this document you must submit five (5) copies of draft labeling.

3. Within the time frames set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Product Manager and the Office of Compliance Monitoring of the problem, the reasons for the problem, and your proposed course of action.

C. End Use Products containing Aldrin alone6/ or in combination with other active ingredients

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division:

a. FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments[5] (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4), attached separately.

c. Formulator's Exemption Statement, if applicable.

2. Within 9 months from receipt of this document you must submit to the Product Manager:

a. Two copies of any product-specific data, if required by Table C.

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[6] The Agency considers all currently registered end-use products to be sole active ingredient formulations. The Agency does not consider solvents or diluents to be insecticidal, and therefore, must be declared as inerts.

b. Product Specific Data Report, if Table C lists required product-specific data.

c. Five copies of draft labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft labeling must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text. End use product labeling must comply specifically with the instructions in Section IV (Regulatory Position and Rationale).

E. Addresses

The required information must be submitted to the following address:

George LaRocca
Product Manager 15
Registration Division (TS-767C)
Office of Pesticide Programs
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460

The address for submissions to the Office of Compliance Monitoring is:

Laboratory Data Integrity Program
Office of Compliance Monitoring (EN-342)
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460.

I. DATA APPENDICES

GUIDE TO TABLES

Tables A, B, and C contain listings of data requirements for the pesticides covered by this Registration Standard.

Table A contains generic data requirements that apply to the pesticide in all products, including data requirements for which a "typical formulation" is the test substance.

Table B contains product-specific data requirements that apply only to a manufacturing use product.

Table C contains product-specific data requirements that apply only to an end use product.

The data tables are generally organized according to the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. The reference numbers accompanying each test refer to the test protocols set out in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161.

2. Test Substance (Column 2). This column lists the composition of the test substance required to be used for the test, as follows:

TGAI = Technical grade of the active ingredient
PAI = Pure active ingredient
PAIRA = Pure active ingredient, radio labeled
TEP = Typical end use formulation
MP = Manufacturing use product
EP = End use product
N/A = Data requirement not applicable to the use pattern

Any other test substances, such as metabolites, will be specifically named in Column 2 or in footnotes to the table.

3. Use pattern (Column 3). This column indicates the use patterns to which the data requirement applies. Use patterns are the same as those given in 40 CFR Part 158. The following letter designations are used for the given use patterns:

A = Terrestrial, food
B = Terrestrial, non-food
C = Aquatic, food
D = Aquatic, non-food
E = Greenhouse, food
F = Greenhouse, non-food
G = Forestry
H = Domestic outdoor
I = Indoor

Any other designations will be defined in a footnote to the table.
4. Does EPA have data? (Column 4). This column indicates one of three answers:

> YES - EPA has data in its files that completely satisfy this data requirement. These data may be cited by other registrants in accordance with data compensation requirements of Part 152, Subpart E.
>
> PARTIALLY - EPA has some data in its files, but such data do not fully satisfy the data requirement. In some cases, the Agency may possess data on one of two required species, or may possess data on one test substance but not all. The term may also indicate that the data available to EPA are incomplete. In this case, when the data are clarified, or additional details of the testing submitted by the original data submitter, the data may be determined to be acceptable. If this is the case, a footnote to the table will usually say so.
>
> NO - EPA either possesses no data which are sufficient to fulfill the data requirement, or the data which EPA does possess are flawed scientifically in a manner that cannot be remedied by clarification or additional information.

5. Bibliographic citation (Column 5). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a GS number if no MRID number has been assigned. Refer to the Bibliography Appendices for a complete citation of the study.

6. Must additional data be submitted? (Column 6). This column indicates whether ~~the~~ data must be submitted to the Agency. If column 3 indicates that the Agency already has data, this column will usually indicate NO. If column 3 indicates that the Agency has only partial data or no data, this column will usually indicate YES. In some cases, even though the Agency does not have the data, EPA will not require its submission because of the unique characteristics of the chemical; because data on another chemical can be used to fulfill the data requirement; or because the data requirement has been waived or reserved. Any such unusual situations will be explained in a footnote to the table.

7. Timeframe for submission (Column 7). It column 5 requires that data be submitted, this column indicates when the data are to be submitted, based on the receipt date of the Registration Standard. The timeframes are those established either as a result of a previous Data Call-In letter, or standardized timeframes established by PR Notice 85-5 (August 22, 1985).

8. Footnotes (at the end of each table). Self-explanatory.

TABLE A
GENERIC DATA REQUIREMENTS FOR ALDRIN

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?1/	Bibliographic Citation 1/	Must Additional Data be Submitted?	Timeframe for Submission2/
§158.120 Product Chemistry						
Product Identity						
61-1 - Product Identity and Disclosure of Ingredients	TGAI	H,I			Yes	6 Months
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	H,I			Yes	6 Months
61-3 - Discussion of Formation of Impurities	TGAI	H,I			Yes	6 Months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis	TGAI	H,I			Yes	12 Months
62-2 - Certification of Limits	TGAI	H,I			Yes	12 Months
62-3 - Analytical Methods to Verify Certified Limit	TGAI	H,I			Yes	12 Months
Physical and Chemical Characteristics						
63-2 - Color	TGAI	H,I			Yes	6 Months
63-3 - Physical State	TGAI	H,I			Yes	6 Months
63-4 - Odor	TGAI	H,I			Yes	6 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR ALDRIN

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?1/	Bibliographic Citation 1/	Must Additional Data be Submitted?	Timeframe for Submission2/
§158.120 Product Chemistry (continued)						
Physical and Chemical Characteristics (continued)						
63-5 - Melting Point	TGAI	H,I			Yes	6 Months
63-6 - Boiling Point	TGAI	H,I			No3/	
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	H,I			Yes	6 Months
63-8 - Solubility	TGAI or PAI	H,I			Yes	6 Months
63-9 - Vapor Pressure	PAI	H,I			Yes	6 Months
63-10 - Dissociation Constant	PAI	H,I			Yes	6 Months
63-11 - Octanol/Water Partition Coefficient	PAI	H,I			Yes	6 Months
63-12 - pH	TGAI	H,I			No4/	
63-13 - Stability	TGAI	H,I			Yes	15 Months (8 Months - Progress Report)
Other Requirements:						
64-1 - Submittal of Samples	TGAI, PAI	H,I			Reserved5/	

1/ Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each pesticide. New requirements have been introduced and previously submitted data must be updated. Therefore, bibliographic citations for the old data are not applicable.

2/ Due dates refer to the number of months following receipt of this Registration Standard by the registrant, unless otherwise indicated.

3/ Not required since aldrin is a solid at room temperature.

4/ Not required since aldrin is practically insoluble in water.

5/ If samples are needed, the Agency will request them.

TABLE A
GENERIC DATA REQUIREMENTS FOR ALDRIN

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission1/
§158.130 Environmental Fate						
DEGRADATION STUDIES-LAB:						
161-1 - Hydrolysis	TGAI or PAIRA	H	No		Yes	9 Months
Photodegradation						
161-2 - In Water	TGAI or PAIRA	H	No		Yes3/	9 Months
161-3 - On Soil	TGAI or PAIRA	N/A				
161-4 - In Air	TGAI or PAIRA	N/A				
METABOLISM STUDIES-LAB:						
162-1 - Aerobic Soil	TGAI or PAIRA	H	No		Yes	27 Months2/ (8 Months - Progress Report)
162-2 - Anaerobic Soil	TGAI or PAIRA	H	No		Yes3/	27 Months2/ (8 Months - Progress Report)
162-3 - Anaerobic Aquatic	TGAI or PAIRA	N/A				
162-4 - Aerobic Aquatic	TGAI or PAIRA	H	No		Yes3/	27 Months2/ (8 Months - Progress Report)
MOBILITY STUDIES:						
163-1 - Leaching and Adsorption/Desorption	TGAI or PAIRA	H	No		Yes	12 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR ALDRIN

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission1/
§158.130 Environmental Fate (continued)						
163-2 - Volatility (Lab)	TEP	N/A				
163-3 - Volatility (Field)	TEP	N/A				
DISSIPATION STUDIES-FIELD:						
164-1 - Soil	TEP	H	No		Yes	27 Months2/ (8 Months- Progress Report)
164-2 - Aquatic (Sediment)	TEP	H	No		Reserved3/	
164-3 - Forestry	TEP	N/A				
164-4 - Combination and Tank Mixes		N/A				
164-5 - Soil, Long-term	TEP	N/A				
ACCUMULATION STUDIES:						
165-1 - Rotational Crops (confined)	PAIRA	N/A				
165-2 - Rotational Crops (field)	TEP	N/A				
165-3 - Irrigated Crops	TEP	N/A				
165-4 - In Fish	TGAI or PAIRA	H	No		Reserved3/	

TABLE A
GENERIC DATA REQUIREMENTS FOR ALDRIN

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission1/
§158.130 Environmental Fate (continued)						
165-5 - In Aquatic Nontarget Organisms	TEP	N/A				
MONITORING STUDIES:						
Water Monitoring Study	TEP	H,I	No		Yes4/	15 Months (90 Days- Acceptable Protocol) (8 Months- Progress Report)
EXPOSURE STUDIES:						
Applicators	TEP	H,I	No		Yes5/	6 Months (90 Days- Acceptable Protocol)
Residents- Indoor Air Monitoring Study	TEP	I	No		Yes6/	(2nd Progress Report-Nov. 1986) (Final Report- June, 1987)

1/ Due dates refer to the number of months following receipt of this Registration Standard by the registrant, unless otherwise indicated.

2/ The first progress report is due 8 months after receipt of this Standard. Interim reports are due semi-annually thereafter.

3/ Because of the detection of residues of chlordane, a related cyclodiene pesticide, in urban water systems, presumably from termiticide uses, additional data requirements have been imposed, which will focus on the fate of aldrin in the aquatic environment. These are: photodegradation in water, anaerobic soil metabolism and aerobic aquatic metabolism. Aquatic (sediment) dissipation data requirements are reserved pending results of the aerobic aquatic metabolism studies. Fish residue accumulation data are reserved pending the results of the octanol/water partition coefficient studies.

4/ A special monitoring study is required, either prospective or retrospective; in which water from sanitary sewers, sumps, and drainage tiles, draining from home foundations treated with aldrin, is sampled and analyzed for residues of aldrin. An acceptable protocol must be submitted within 90 days of receipt of this Standard.

5/ Applicator exposure data, must be submitted to support the termiticide use. An acceptable protocol must be submitted within 90 days of receipt of this Standard.

6/ This requirement was originally imposed as part of the Agency's 1984 Termiticide Data Call-In program. This study is currently in progress. Further testing may be required pending the results of this study.

TABLE A
GENERIC DATA REQUIREMENTS FOR ALDRIN

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission[1]/
§158.135 Toxicology						
ACUTE TESTING:						
81-1 - Acute Oral Toxicity - Rat	TGAI	H,I	No		Yes	9 Months
81-2 - Acute Dermal Toxicity - Rabbit	TGAI	H,I	No		Yes	9 Months
81-3 - Acute Inhalation Toxicity - Rat	TGAI	H,I	No		Yes	9 Months
81-7 - Delayed Neurotoxicity - Hen	TGAI	H,I	No		No[2]/	
SUBCHRONIC TESTING:						
82-1 - 90-Day Feeding: Rodent and Nonrodent (Dog)	TGAI	H,I	Partially	00103736 00085416	No[3]/	
82-2 - 21-Day Dermal - Rabbit	TGAI	H,I	No		Reserved[4]/	
82-3 - 90-Day Dermal - Rabbit	TGAI	H,I	No		No[5]/	
82-4 - 90-Day Inhalation - Rat	TEP	H,I	No		No[6]/	
82-5 - 90-Day Neurotoxicity - Hen	TGAI	H,I	No		No[2]/	
- Mammal						

TABLE A
GENERIC DATA REQUIREMENTS FOR ALDRIN

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission[1/]
§158.135 Toxicology (continued)						
CHRONIC TESTING:						
83-1 - Chronic Toxicity - Rodent and Nonrodent	TGAI	H,I	Yes	00085416, GS0172-001	No	
83-2 - Oncogenicity - Mouse	TGAI	H,I	Yes	GS0172-001	No	
Rat	TGAI	H,I	No		Yes	50 Months[10/] (8 Months- Progress Report)
83-3 - Teratogenicity - Rat and Rabbit	TGAI	H,I	No		Yes	15 Months (8 Months- Progress Report)
83-4 - Reproduction - Rat 2-generation	TGAI	H,I	No		Yes	39 Months[10/] (8 Months- Progre Report)
MUTAGENICITY TESTING:						
84-2 - Gene Mutation (Ames Test)	TGAI	H,I	No		Yes[7/][11/]	9 Months
84-2 - Structural Chromosomal Aberration	TGAI	H,I	Partially	00123771	Yes[8/][11/]	12 Months
84-4 - Other Genotoxic Effects	TGAI	H,I	Partially	00109564	Yes[9/][11/]	12 Months (90 Days- Acceptab Protocol)

TABLE A
GENERIC DATA REQUIREMENTS FOR ALDRIN

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission9/
SPECIAL TESTING:						
85-1 - General Metabolism	PAI or PAIRA	H,I	Yes	00151872 00151879	No12/	

1/ Due dates refer to the number of months following receipt of the Registration Standard by the registrant, unless otherwise indicated.

2/ Aldrin is dissimilar to known delayed neurotoxic agents (i.e., organophosphates) and neurotoxicity of the delayed type has not been reported in the large number of chemical plant intoxications encountered. Recovery has been complete and relatively rapid when humans were removed from the exposure area. For these reasons, the Agency is not requiring this test.

3/ The Agency is not requiring 90-day studies since the Agency has acceptable chronic feeding studies in the rat and dog, and these supercede the need for subchronic studies.

4/ Requirement for submission of a 21-day dermal study is reserved pending the results of the acute dermal toxicity study.

5/ The Agency recognizes that aldrin is absorbed dermally and toxicity can ensure from that exposure. However, the target organs have been well delineated from other routes of exposure and therefore, no data are required for this area of study.

6/ This requirement was originally imposed as part of the Agency's 1984 Data Call-In Notice. The Agency has subsequently determined that this study is not necessary, recognizing that absorption of aldrin by the oral route will suffice to determine the toxic end points or target organs to be determined in a 90-day inhalation study.

7/ Mammalian cell gene mutation assays, with mouse lymphoma (L5178Y/TK), or Chinese hamster (CHO/V79/HGPRT) cells *inter alia*, specifically comparing activation systems (S9) derived from rat vs. mouse (or hamster) liver microsomes, are required.

8/ Somatic cell cytogenetic assays, either *in vitro* or *in vivo*, are required.

TABLE A

GENERIC DATA REQUIREMENTS FOR ALDRIN

§158.135 Toxicology (continued)

9/ The following studies are required:

a. repair in mammalian cell systems, e.g., primary mouse hepatocytes or established cell lines, by autoradiographic or alkaline elution techniques.

b. adequately controlled promotion assays, e.g., in cell lines already initiated (by viral transformation), or exposed to known active chemical initiators.

c. mammalian cell transformation in systems with an established data base, e.g., C3H 10 T1/2, BALB 3T3, *inter alia*.

d. assays for mitotic spindle effects (*in vitro* or *in vivo*), and/or involving other cellular mechanisms (e.g., oncogene activation), *inter alia*.

e. assays which can distinguish effects on replicative S-phase (scheduled) DNA synthesis from UDS, e.g., in primary hepatocytes from several species (mouse vs. rat/hamster).

Acceptable protocols for the mitotic spindle effects and mammalian cell transformation tests must be submitted within 90 days from receipt of the Guidance Document. Protocols for the other tests are not required to be submitted, since acceptable protocols for these tests can be found in the EPA Guidelines.

10/ The first progress report is due 8 months after receipt of this Standard. Interim reports are due semi-annually thereafter.

11/ This requirement was originally imposed as part of the Agency's 1984 Special Termiticide Data Call-In Notice. Data received in response to that DCI were reviewed in conjunction with the development of this Registration Standard and found to be unacceptable.

12/ This requirement was originally imposed as part of the Agency's 1984 Special Termiticide Data Call-In Notice. Acceptable data have been received by the Agency.

TABLE A
GENERIC DATA REQUIREMENTS FOR ALDRIN

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.145 Wildlife and Aquatic Organisms						
AVIAN AND MAMMALIAN TESTING:						
71-1 - Acute Avian Oral Toxicity	TGAI	H,I	Yes	00020560 1/ 00111910 1/	No	
71-2 - Avian Subacute Dietary Upland Game Bird and Waterfowl	TGAI	H,I	Yes	00022923	No	
71-3 - Wild Mammal Toxicity	TGAI	N/A				
71-4 - Avian Reproduction Upland Game Bird and Waterfowl	TGAI	H,I	No		Reserved 2/	
71-5 - Simulated Field Testing and Actual Field Testing - Mammals and Birds	TEP	H,I	No		Reserved 2/	
72-1 - Freshwater Fish Toxicity Coldwater and Warmwater Species	TGAI	H,I	Yes	00003503	No	
AQUATIC ORGANISM TESTING:						
72-2 - Acute Toxicity to Freshwater Invertebrates	TGAI	H,I	Yes	00003503	No	
72-3 - Acute Toxicity to Estuarine and Marine Organisms	TGAI	H,I	No		Reserved 2/	

TABLE A
GENERIC DATA REQUIREMENTS FOR ALDRIN

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.145 Wildlife and Aquatic Organisms (continued)						
72-4 - Fish Early Life Stage, and Aquatic Invertebrate Life Cycle	TGAI	H,I	No		Reserved2/	
72-5 - Fish - Life Cycle	TGAI	H,I	No		Reserved2/	
72-6 - Aquatic Organism Accumulation	TGAI, PAI or Degradation Product	H,I	No		Reserved2/	
72-7 - Simulated Field Testing and Actual Field Testing - Aquatic Organisms	TEP	H,I	No		Reserved2/	
SPECIAL TESTING						
70-1 Aquatic Residue Monitoring		H,I	No		Reserved2/	

1/ The data cited together will fulfill the data requirement.

2/ This requirement is reserved pending the results of the special monitoring study, in which water from sanitary sewer, sumps, and drainage tiles, draining from home foundations treated with aldrin, is sampled and analyzed for residues of aldrin.

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING ALDRIN

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?[1]	Bibliographic Citation [1]	Must Additional Data be Submitted?	Timeframe for Submission[2]
§158.120 Product Chemistry						
Product Identity:						
61-1 - Product Identity and Disclosure of Ingredients	MP[3]	H,I			Yes	6 Months
61-2 - Description of Beginning Materials and Manufacturing Process	MP	H,I			Yes	6 Months
61-3 - Discussion of Formation of Impurities	MP	H,I			Yes	6 Months
Analysis and Certification of Product Ingredients:						
62-1 - Preliminary Analysis	MP	H,I			Yes	12 Months
62-2 - Certification of Limits	MP	H,I			Yes	12 Months
62-3- Analytical Methods to Verify Certified Limit	MP	H,I			Yes	12 Months
Physical And Chemical Characteristics:						
63-2 - Color	MP	H,I			Yes	6 Months
63-3 - Physical State	MP	H,I			Yes	6 Months
63-4 - Odor	MP	H,I			Yes	6 Months

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING ALDRIN

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?1/	Bibliographic Citation 1/	Must Additional Data be Submitted?	Timeframe for Submission2/
§158.120 Product Chemistry (continued)						
Physical and Chemical Characteristics (continued)						
63-7 - Density, Bulk Density, or Specific Gravity	MP	H,I			Yes	7 Months
63-12 - pH	MP	H,I			No4/	
63-14 - Oxidizing or Reducing Action	MP	H,I			Yes	7 Months
63-15 - Flammability	MP	H,I			Yes	7 Months
63-16 - Explodability	MP	H,I			Yes	7 Months
63-17 - Storage Stability	MP	H,I			Yes	16 Months- (8 Months- Progress Report)
63-18 - Viscosity	MP	H,I			Yes	7 Months
63-19 - Miscibility	MP	H,I			Yes	7 Months
63-20 - Corrosion Characteristics	MP	H,I			Yes	7 Months

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING ALDRIN

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?1/	Bibliographic Citation 1/	Must Additional Data be Submitted?	Timeframe for Submission2/
Other Requirements:						
64-1 - Submittal of Samples	MP	H,I			Reserved5/	

1/ Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each manufacturing-use product. New requirements have been introduced and previously submitted data must be updated. Therefore, bibliographic citations for the old data are not applicable.

2/ Due dates refer to the number of months following receipt of this Registration Standard by the registrant, unless otherwise indicated.

3/ The technical (T) also serves as a manufacturing-use product, since aldrin is not manufactured in the United States of America. All formulation intermediates are included in the category of manufacturing-use products.

4/ Not required since aldrin is practically insoluble in water.

5/ If samples are needed, the Agency will request them.

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING ALDRIN

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission[1/]
ACUTE TESTING:						
81-1 - Acute Oral Toxicity - Rat	MP	H,I	No		Yes	9 Months
81-2 - Acute Dermal Toxicity - Rabbit	MP [2/]	H,I	No		Yes	9 Months
81-3 - Acute Inhalation Toxicity - Rat	MP	H,I	No		Yes	9 Months
81-4 - Primary Eye Irritation - Rabbit	MP	H,I	No		Yes	9 Months
81-5 - Primary Dermal Irritation - Rabbit	MP	H,I	No		Yes	9 Months
81-6 - Dermal Sensitization - Guinea Pig	MP	H,I	No		No[3/]	

[1/] Due dates refer to the number of months following receipt of this Registration Standard by the registrant, unless otherwise indicated.

[2/] The technical (T) also serves as a manufacturing-use product since aldrin is not manufactured in the United States of America. All formulation intermediates are included in the category of manufacturing-use products.

[3/] Due to the extensive human exposure data compiled without reported dermal sensitization, testing is not required.

TABLE C
PRODUCT SPECIFIC DATA REQUIREMENTS FOR END-USE PRODUCTS CONTAINING ALDRIN

Guideline Citation and Name of Test	Test Substance	Use Patterns	Does EPA Have Data?1/	Bibliographic Citation1/	Must Additional Data be Submitted?	Timeframe for Submission2/
§158.120 - Product Chemistry						
Product Identity:						
61-1 - Product Identity and Disclosure of Ingredients	EP	H,I			Yes	6 Months
61-2 - Description of Beginning Materials and Manufacturing Process	EP	H,I			Yes	6 Months
61-3 - Discussion of Formation of Impurities	EP	H,I			Yes	6 Months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis	EP	H,I			Yes	12 Months
62-1 - Certification of Limits	EP	H,I			Yes	6 Months
62-3 - Analytical Methods to Verify Certified Limit	EP	H,I			Yes	6 Months
Physical and Chemical Characteristics						
63-2 - Color	EP	H,I			Yes	6 Months
63-3 - Physical State	EP	H,I			Yes	6 Months
63-4 - Odor	EP	H,I			Yes	6 Months
63-7 - Density, Bulk Density, or Specific Gravity	EP	H,I			Yes	6 Months

TABLE C
PRODUCT SPECIFIC DATA REQUIREMENTS FOR END-USE PRODUCTS CONTAINING ALDRIN

Guideline Citation and Name of Test	Test Substance	Use Patterns	Does EPA Have Data?1/	Bibliographic Citation1/	Must Additional Data be Submitted?	Timeframe for Submission2/
§158.120 - Product Chemistry (continued)						
Physical and Chemical Characteristics (continued)						
63-12 - pH	EP	H,I			Yes	6 Months
63-14 - Oxidizing or Reducing Action	EP	H,I			Yes	6 Months
63-15 - Flammability	EP	H,I			Yes	6 Months
63-16 - Explodability	EP	H,I			Yes	6 Months
63-17 - Storage Stability	EP	H,I			Yes	12 Months
63-18 - Viscosity	EP	H,I			Yes	6 Months
63-19 - Miscibility	EP	H,I			Yes	6 Months
63-20 - Corrosion Characteristics	EP	H,I			Yes	6 Months
63-21 - Dielectric Breakdown Voltage	EP	H,I			No3/	
Other Requirements:						
64- 1 Submittal of Samples	EP,TGAI, PAI	H,I			Reserved4/	

1/ Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each pesticide. New requirements have been introduced and previously submitted data must be updated. Therefore, bibliographic citations for the old data are not applicable.

2/ Due dates refer to the number of months following receipt of this Registration Standard by the registrant, unless otherwise indicated.

3/ Not required because product Labels caution to avoid use near electrical equipment.

4/ If samples are needed, the Agency will request them.

TABLE C

PRODUCT SPECIFIC DATA REQUIREMENTS FOR END-USE PRODUCTS CONTAINING ALDRIN

Guideline Citation and Name of Test	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission[1/]
§158.135 Toxicology						
Acute Testing:						
81-1 - Acute Oral Toxicity - Rat	EP	H,I	No		Yes	9 Months
81-2 - Acute Dermal Toxicity - Rabbit	EP	H,I	No		Yes	9 Months
81-3 - Acute Inhalation Toxicity - Rat	EP	H,I	No		Yes	9 Months
81-4 - Primary Eye Irritation - Rabbit	EP	H,I	No		Yes	9 Months
81-5 - Primary Dermal Irritation - Rabbit	EP	H,I	No		Yes	9 Months
81-6 - Dermal Sensitzation	EP	H,I	No		No[2/]	
SPECIAL TEST						
Guinea Pig Inhalation Study	EP	H,I	No		Yes[3/]	15 Months (90 Days-Acceptable Protocol) (8 Months- Progress Report)

1/ Due dates refer to the number of months following receipt of this Registration Standard by the registrant, unless otherwise indicated.

2/ Due to the extensive human exposure data compiled without reported dermal sensitization, testing is not required.

3/ Testing is required to delineate the irritative capabilities to mucous membranes of aldrin, the solvent, and/or the combination. The study design must include a 7-day exposure period to two groups of guinea pigs, with a 2-week recovery in one group; the second to be sacrificed after 7 days of exposure. Exposures should be for 6-8 hrs/day at levels found in a house on day 1 of termite treatment and include end-use solvent alone; aldrin alone, and solvent plus aldrin. Registrants of products containing the same or similar solvents are encouraged to develop data jointly.

II. LABELING APPENDICES

SUMMARY-1

LABEL CONTENTS

40 CFR 162.10 requires that certain specific labeling statements appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to the table at the end of this Appendix.

Item 1. PRODUCT NAME - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading.

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text.

Item 3. NET CONTENTS - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. [40 CFR 162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. [40 CFR 162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container. [40 CFR 162.10(f)]

Item 6A. INGREDIENTS STATEMENT - An ingredients statement is required on the front panel. The ingredients statement must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. [40 CFR 162.10(g)]

SUMMARY-2

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

Size of Label on Front Panel in Square Inches	Signal Word Minimum Type Size All Capitals	"Keep Out of Reach of Children" Minimum Type Size
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely. [40 CFR 162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (DANGER, WARNING, or CAUTION) is required on the front panel immediately below the child hazard warning statement. [40 CFR 162.10 (h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON. [40 CFR 162.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. [40 CFR 162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. [40 CFR 162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. [40 CFR 162.10(h)(2)].

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. [40 CFR 162.10(h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. [40 CFR 162.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD - FLAMMABILITY Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in the PHYS/CHEM Labeling Appendix. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

Item 9A. RESTRICTED USE CLASSIFICATION - FIFRA sec. 3(d) requires that all pesticide formulations/uses be classified for either general or restricted use. Products classified for restricted use may be limited to use by certified applicators or persons under their direct supervision (or may be subject to other restrictions that may be imposed by regulation).

In the Registration Standard, the Agency has (1) indicated certain formulations/uses are to be restricted (Section IV indicates why the product has been classified for restricted use); or (2) reserved any classification decision until appropriate data are submitted.

The Regulatory Position and Rationale states whether products containing this active ingredient are classified for restricted use. If they are restricted the draft label(s) submitted to the Agency as part of your application must reflect this determination (see below).

If you do not believe that your product should be classified for restricted use, you must submit any information and rationale with your application for reregistration. During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of 40 CFR 162.11(c). You will be notified of the Agency's classification decision.

Classification Labeling Requirements

If your product has been classified for restricted use, the following label requirements apply:

1. All uses restricted.

a. The statement "Restricted Use Pesticide" must appear at the top of the front panel of the label. The statement must be set in type of the same minimum size as required for human hazard signal word (see table in 40 CFR 162.10(h)(1)(iv)

b. Directly below this statement on the front panel, a summary statement of the terms of restriction must appear (including the reasons for restriction if specified in Section I). If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

2. Some but not all uses restricted. If the Regulatory Position and Rationale states that some uses are classified for restricted use, and some are unclassified, several courses of action are available:

a. You may label the product for Restricted use. If you do so, you may include on the label uses that are unrestricted, but you may not distinguish them on the label as being unrestricted.

b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses.

c. You may "split" your registration, i.e., register two separate products with identical formulations, one bearing only unrestricted uses, and the other bearing restricted uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the products will be assigned separate registration numbers.

Item 9B. MISUSE STATEMENT - All products must bear the misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." This statement appears at the beginning of the directions for use, directly beneath the heading of that section.

Item 10A. REENTRY STATEMENT - If a reentry interval has been established by the Agency, it must be included on the label. Additional worker protection statements may be required in accordance with PR Notice 83-2, March 29, 1983.

Item 10B. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix II, STOR, PEST/DIS, and CONT/DIS to determine the storage and disposal instructions appropriate for your products.

Item 10C. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. [40 CFR 162.10]

COLLATERAL LABELING

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other written or graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

SUMMARY-6

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

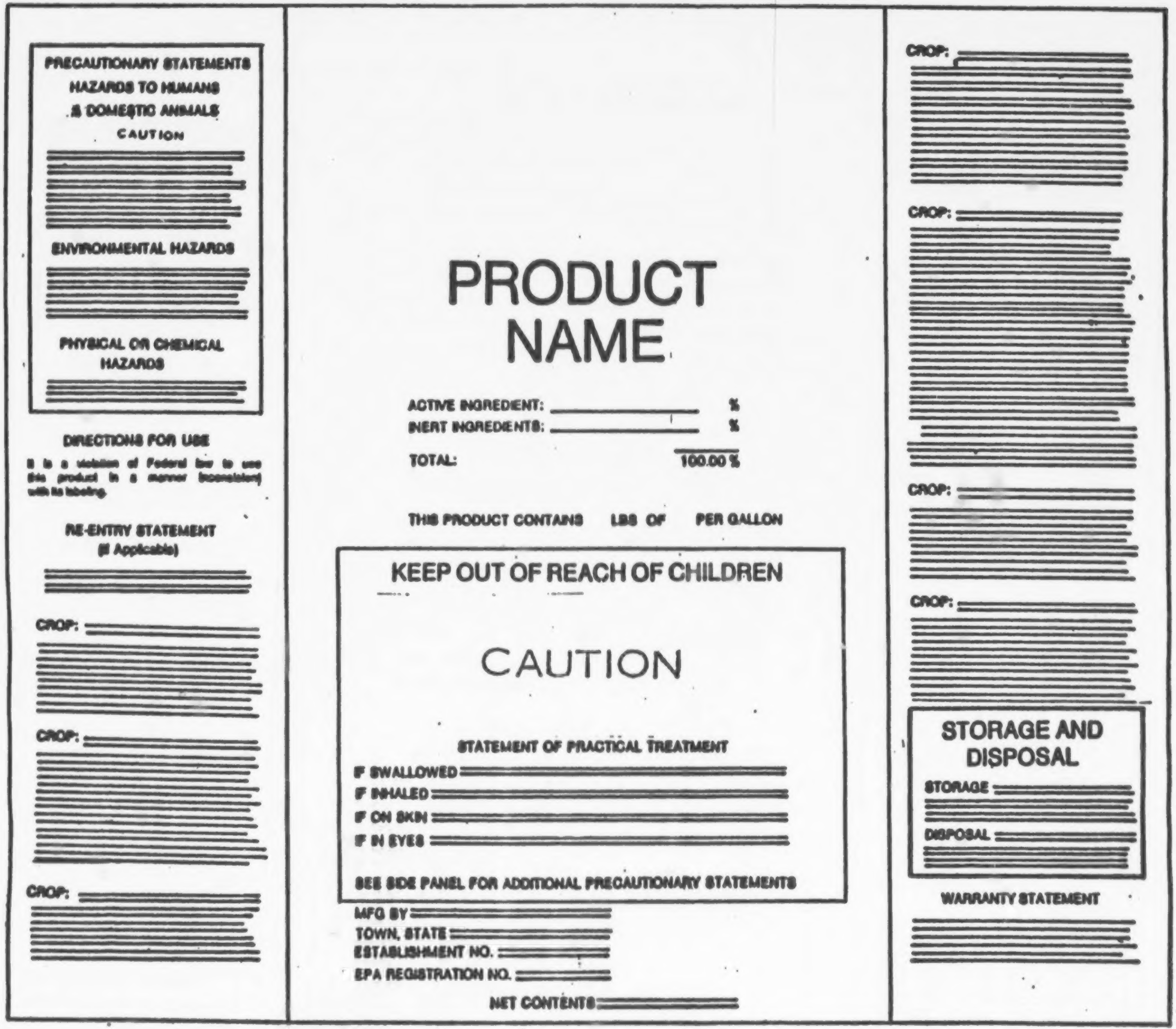
ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Reg. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Est. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

SUMMARY-7

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & crossbones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of Practical Treatment or First Aid	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

SUMMARY-8

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	Refer to Appendix II guide PHYS/CHEM
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9B	Misuse statement	All products	Immediately following heading of directions for use		Required statement is: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."
10A	Reentry statement	PR Notice 83-2 or as determined by the Agency	In the directions for use	Immediately after misuse statement	
10B	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from from other directions for use. Refer to Appendix II guides STOR, CONT/DIS, and PEST/DIS for further information and required statements.
10C	Directions for use	All products	None	None	May be in metric as well as U.S. units



PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS
& DOMESTIC ANIMALS
CAUTION

ENVIRONMENTAL HAZARDS

PHYSICAL OR CHEMICAL HAZARDS

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

RE-ENTRY STATEMENT
(If Applicable)

CROP:

CROP:

CROP:

PRODUCT
NAME

ACTIVE INGREDIENT: %
INERT INGREDIENTS: %
TOTAL: 100.00 %

THIS PRODUCT CONTAINS LBS OF PER GALLON

KEEP OUT OF REACH OF CHILDREN

CAUTION

STATEMENT OF PRACTICAL TREATMENT
IF SWALLOWED
IF INHALED
IF ON SKIN
IF IN EYES

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

MFG BY
TOWN, STATE
ESTABLISHMENT NO.
EPA REGISTRATION NO.

NET CONTENTS

CROP:

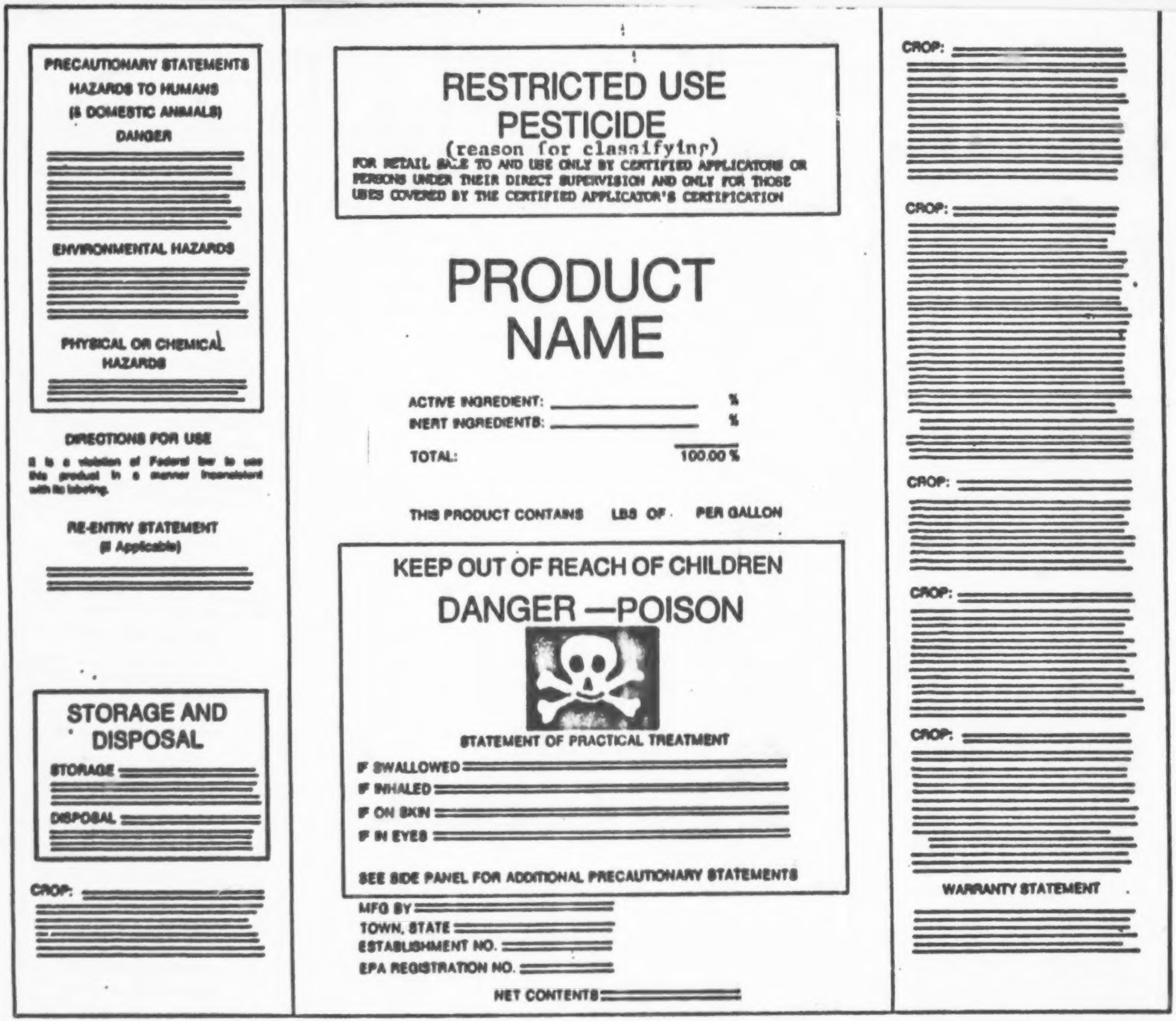
CROP:

CROP:

CROP:

STORAGE AND DISPOSAL
STORAGE
DISPOSAL

WARRANTY STATEMENT



PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS
(& DOMESTIC ANIMALS)
DANGER

ENVIRONMENTAL HAZARDS

PHYSICAL OR CHEMICAL
HAZARDS

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

RE-ENTRY STATEMENT
(If Applicable)

STORAGE AND
DISPOSAL

STORAGE

DISPOSAL

CROP:

RESTRICTED USE
PESTICIDE
(reason for classifying)

FOR RETAIL SALE TO AND USE ONLY BY CERTIFIED APPLICATORS OR PERSONS UNDER THEIR DIRECT SUPERVISION AND ONLY FOR THOSE USES COVERED BY THE CERTIFIED APPLICATOR'S CERTIFICATION

PRODUCT
NAME

ACTIVE INGREDIENT: ______ %
INERT INGREDIENTS: ______ %
TOTAL: 100.00 %

THIS PRODUCT CONTAINS LBS OF PER GALLON

KEEP OUT OF REACH OF CHILDREN
DANGER —POISON

STATEMENT OF PRACTICAL TREATMENT

IF SWALLOWED
IF INHALED
IF ON SKIN
IF IN EYES

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

MFG BY
TOWN, STATE
ESTABLISHMENT NO.
EPA REGISTRATION NO.
NET CONTENTS

CROP:

CROP:

CROP:

CROP:

CROP:

WARRANTY STATEMENT

~~cant obtained the data from another firm (identify); applicant copied data from a publication; applicant obtained a copy of the data from EPA).~~

~~(d) The applicant shall submit with his application a statement that EPA, in its evaluation of the properties, efficacy, and safety of the formulated end-use product, may not consider any data as supporting the application, except the following data:~~

~~(1) The data the applicant has submitted to EPA under paragraph (b) of this section;~~

~~(2) Other data pertaining to the safety of the product's active ingredients, rather than to the safety of the end-use product; and~~

~~(3) Existing tolerances, food additive regulations, exemptions, and other clearances issued under the Federal Food, Drug, and Cosmetic Act.~~

~~(e) If the applicant knows that any item of data he submitted under this section was generated by (or at the expense of) another person who originally submitted the data to EPA (or its predecessor, USDA) on or after January 1, 1970, to support an application for registration, experimental use permit, or amendment adding a new use to an existing registration, or for reregistration (unless the applicant and the original data submitter have reached written agreement on the amount and the terms of payment of any compensation that may be payable under FIFRA section 3(c)(1)(D)(ii) with regard to approval of the application), the applicant shall submit to EPA a statement that he has furnished to each such identified original data submitter:~~

~~(1) A notification of the applicant's intent to apply for registration, including the proposed product name;~~

~~(2) An offer to pay the person compensation, with regard to the approval of the application, to the extent required by FIFRA sections 3(c)(1)(D) and 3(c)(2)(D);~~

~~(3) An identification of the item(s) of data to which the offer applies;~~

~~(4) An offer to commence negotiations to ascertain the amount and terms of compensation to be paid; and~~

~~(5) The applicant's name, address and telephone number.~~

~~(f) If the applicant's product contains any active ingredient other than those that are present solely because of the incorporation into the product, during formulation, of one or more other registered pesticide products purchased from another producer, then the applicant shall also comply with § 162.9–5 as to such active ingredient, and the application shall contain an acknowledgment that for purposes of FIFRA section 3(c)(1)(D) the application relies on (and any resulting registration should be regarded as if it were based on the Administrator's consideration of) the following data:~~

~~(1) All data submitted or specifically cited by the applicant in support of the registration; and~~

~~(2) Each other item of data in the Agency's files which:~~

~~(i) Concerns the properties or effects of any such active ingredient; and~~

~~(ii) Is one of the types of data that EPA would require to be submitted for scientific review by EPA if the applicant sought the initial registration under FIFRA Section 3(c)(5) of a product with composition and intended uses identical to those proposed for the applicant's product, under the data requirements in effect on the date EPA approves the applicant's present application.~~

~~(Secs. 3, 6, and 25 of FIFRA, as amended, 7 U.S.C. 136 *et seq.*)~~

~~[44 FR 27963, May 11, 1979]~~

§ 162.10 Labeling requirements.

(a) *General*—(1) *Contents of the label.* Every pesticide products shall bear a label containing the information specified by the Act and the regulations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

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(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) *Prominence and legibility.* (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) *Language to be used.* All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) *Placement of Label*—(i) *General.* The label shall appear on or be securely attached to the immediate container of the pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) *Tank cars and other bulk containers*—(A) *Transportation.* While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170-189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) *Storage.* When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) *False or misleading statements.* Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 162.15, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

(6) *Final printed labeling.* (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) *Name, brand, or trademark.* (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 162.6(b)(4).

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for * * *," "Distributed by * * *," or "Sold by * * *" to show that the name is not that of the producer.

(d) *Net weight or measure of contents.* (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68° F (20°C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semisolid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(e) *Product registration number.* The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run parallel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) *Producing establishments registration number.* The producing establishment registration number preceded by the phrase "EPA Est.", of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) *Ingredient statement*—(1) *General.* The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) *Position of ingredient statement.* (i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) *Names to be used in ingredient statement.* The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of Section 25(c)(6).

(4) *Statements of percentages.* The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) *Accuracy of stated percentages.* The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) *Deterioration.* Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) *Inert ingredients.* The Administrator may require the name of any inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) *Warnings and precautionary statements.* Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups; those required on the front panel of the labeling and those which may appear elsewhere. Specific requir ments concerning content, placemen type size, and prominence are give below.

(1) *Required front panel statement* With the exception of the chil hazard warning statement, the text re quired on the front panel of the lab is determined by the Toxicity Categ ry of the pesticide. The category is a signed on the basis of the highe hazard shown by any of the indicato in the table below:

Hazard indicators	Toxicity categories			
	I	II	III	IV
Oral LD₅₀	Up to and including 50 mg/kg.	From 50 thru 500 mg/kg	From 500 thru 5000 mg/kg.	Greater than 5000 mg/kg.
Inhalation LC₅₀	Up to and including .2 mg/liter.	From .2 thru 2 mg/liter	From 2. thru 20 mg/liter	Greater than 20 mg/li
Dermal LD₅₀	Up to and including 200 mg/kg.	From 200 thru 2000	From 2,000 thru 20,000	Greater than 20,000.
Eye effects	Corrosive; corneal opacity not reversible within 7 days.	Corneal opacity reversible within 7 days; irritation persisting for 7 days.	No corneal opacity; irritation reversible within 7 days.	No irritation.
Skin effects	Corrosive	Severe irritation at 72 hours.	Moderate irritation at 72 hours.	Mild or slight irritation 72 hours.

(i) *Human hazard signal word*—(A) *Toxicity Category I.* All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) *Toxicity Category II.* All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) *Toxicity Category III.* All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) *Toxicity Category IV.* All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) *Use of signal words.* Use of any signal word(s) associated with a higher Toxicity Category is not permitte except when the Agency determine that such labeling is necessary to pr vent unreasonable adverse effects o man or the environment. In no ca shall more than one human hazar signal word appear on the front pan of a label.

(ii) *Child hazard warning.* Every pe ticide product label shall bear on th front panel the statement "keep out o reach of children." Only in cas where the likelihood of contact wit children during distribution, marke ing, storage or use is demonstrated b the applicant to be extremely remot or if the nature of the pesticide is suc that it is approved for use on infant or small children, may the Administra tor waive this requirement.

(iii) *Statement of practical trea ment*—(A) *Toxicity Category I.* statement of practical treatment (fir aid or other) shall appear on the fron panel of the label of all pesticides fal ing into Toxicity Category I on th basis of oral, inhalation or dermal to icity. The Agency may, howeve permit reasonable variations in th placement of the statement of pract

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cal treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) *Other toxicity categories.* The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) *Placement and prominence.* All the require front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

Size of label front panel in square inches	Points	
	Required signal word, all capitals	"Keep out of reach of Children"
5 and under	6	6
Above 5 to 10	10	6
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	18	12

(2) *Other required warnings and precautionary statements.* The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) *Hazard to humans and domestic animals.* (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity category	Precautionary statements by toxicity category	
	Oral, inhalation, or dermal toxicity	Skin and eye local effects
I	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Front panel statement of practical treatment required.].	Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Appropriate first aid statement required.]
II	May be fatal if swallowed [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statements required.].	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.]
III	Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.].	Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.
IV	[No precautionary statements required.]	[No precautionary statements required.]

(ii) *Environmental hazards.* Where a hazard exists to non target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or damage. Examples of the hazard statements and the circumstances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD_{50} of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC_{50} of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD_{50} of 100 mg/kg or less, or a subacute dietary LC_{50} of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) *Physical or chemical hazards.* Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

Flash point	Required text
(A) PRESSURIZED CONTAINERS	
Flash point at or below 20° F; if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
Flash point above 20° F and not over 80° F or if the flame extension is more than 18 in long at a distance of 6 in from the flame.	Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
All other pressurized containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
(B) NONPRESSURIZED CONTAINERS	
At or below 20° F	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
Above 20° F and not over 80° F	Flammable. Keep away from heat and open flame.
Above 80° F and not over 150° F	Do not use or store near heat or open flame.

(i) *Directions for Use*—(1) *General requirements*—(i) *Adequacy and clarity of directions.* Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) *Placement of directions for use.* Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular:" and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) *Exceptions to requirement for direction for use*—(A) Detailed directions for use may be omitted from labeling of pesticides which are intended for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

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(*1*) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(*2*) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(*3*) The product will not come into the hands of the general public except after incorporation into finished products; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(*1*) The label clearly states that the product is for use only by physicians or veterinarians;

(*2*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(*3*) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(*1*) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(*2*) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(*3*) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(3) *Contents of Directions for Use.* The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in 162.10(j) immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment required.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning (See Table in § 162.10(h)(1)(iv).)

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) *Statement of Use Classification.* By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j)(1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of § 162.10(j)(2).

(1) *General Use Classification.* Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) *Restricted Use Classification.* Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) *Front panel statement of restricted use classification.* (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in § 162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

(k) Advertising. [Reserved]

[40 FR 28268, July 3, 1975; 40 FR 32329, Aug. 1, 1975; 40 FR 36571, Aug. 21, 1975, as amended at 43 FR 5786, Feb. 9, 1978]

~~§ 162.11 Criteria for determinations of unreasonable adverse effects.~~

~~(a) *Criteria for Issuance of Notice of Intent to Deny Registration, Cancel Registration, or to Hold a Hearing*.—(1) *Presumption.* (i) A rebuttable presumption shall arise that a notice of intent to deny registration pursuant to section 3(c)(6) of the Act, a notice of intent to cancel registration pursuant to section 6(b)(1) of the Act, or a notice of intent to hold a hearing to determine whether the registration should be cancelled or denied, as appropriate, shall be issued, upon a determination by the Administrator that the pesticide meets or exceeds any of the criteria for risk set forth in paragraph (a)(3) of this section. Upon such determination, the Administrator shall issue notice by certified mail to the applicant or registrant, as the case may be, stating that the applicant or registrant has the opportunity to submit evidence in rebuttal of such presumption in accordance with paragraph (a)(4) of this section. The applicant or registrant shall have forty-five (45) days from the date such notice is sent to submit evidence in rebuttal of the presumption; provided, however, that for good cause shown the Administrator may grant an additional sixty~~

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PHYS/CHEM-1

PHYSICAL/CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. All Other Pressurized Containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and not over 80°F.	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STOR-1

STORAGE INSTRUCTIONS FOR PESTICIDES

Heading:

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL."

Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

CONT/DIS-1

CONTAINER DISPOSAL INSTRUCTIONS

The label of each product must bear container disposal instructions appropriate to the type of container.

1. Domestic use products must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. All other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording)

1/ Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

PESTICIDE DISPOSAL INSTRUCTIONS

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients that are Acute Hazardous Wastes (see list in this Appendix) or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, skin or eye irritation potential, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

> "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

3. The labels of all products, except those intended for domestic use, containing active or inert ingredients that are Toxic Hazardous Wastes (see list in this Appendix) or meet any of the criteria in 40 CFR 261, Subpart C for a hazardous waste must bear the following pesticide disposal statement:

> "Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

4. Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

> "Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

5. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

PEST/DIS-2

PESTICIDE ACTIVE INGREDIENTS THAT ARE ACUTE HAZARDOUS WASTES

I. PESTICIDES ON THE "E" LIST (with RCRA # and CAS
[40 CFR 261.33(e)]

Acrolein	P003	107-13-1
Aldicarb	P070	116-06-3
Aldrin	P004	309-00-2
Allyl alcohol	P005	107-18-6
Aluminum phosphide	P006	1302-45-0
4-Aminopyridine (Avitrol)	P008	504-24-5
Arsenic acid	P010	7778-39-4
Arsenic pentoxide	P011	1303-28-2
Arsenic trioxide	P012	1327-53-3
Calcium cyanide	P021	592-01-8
Carbon disulfide	P022	75-15-0
p-Chloroaniline	P024	106-47-8
Cyanides (soluble cyanide salts not otherwise specified)	P030	
Cyanogen chloride	P031	506-77-4
Dieldrin	P037	60-57-1
O,O-Diethyl S-[2-ethylthio)ethyl] phosphorodithioate (disulfoton)	P039	298-04-4
O,O-Diethyl O-pyrazinyl phosphorothioate (Zinophos®)	P040	297-97-2
Dimethoate	P044	60-51-5
O,O-Dimethyl O-p-nitrophenyl. phosphorothioate (methyl parathion)	P071	298-00-0
4,6-Dinitro-o-cresol and salts	P047	534-52-1
4,6-Dinitro-o-cyclohexylphenol	P034	131-89-5
Dinoseb	P020	88-85-7
Endosulfan	P050	115-29-7
Endothall	P088	129-67-9
Endrin	P051	72-20-8
Famphur	P097	52-85-7
Fluoroacetamide	P057	640-19-7
Heptachlor	P059	76-48-8
Hexachlorohexahydro-exo,exo-dimethanonaphthalene (Isodrin)	P069	465-73-6
Hydrocyanic acid	P063	74-90-8
Methomyl	P066	16752-77-5
alpha-Naphthylthiourea (ANTU)	P072	86-88-41
Nicotine and salts	P075	54-11-5
Octamethylpyrophosphoramide (OMPA, schradan)	P085	152-16-9
Parathion	P089	56-38-2
Phenylmercuric acetate (PMA)	P092	62-38-4
Phorate	P094	298-02-2
Potassium cyanide	P098	151-50-8
Propargyl alcohol	P102	107-19-7
Sodium azide	P105	26628-22-8
Sodium cyanide	P106	143-33-9
Sodium fluoroacetate	P058	62-74-8

Strychnine and salts	P108	57-24-9 60-41-3
O,O,O,O-Tetraethyl dithiopyrophosphate (sulfotepp)	P109	3689-24-5
Tetraethyl pyrophosphate	P111	107-49-3
Thallium sulfate	P115	7446-18-6
Thiofanox	P045	39196-18-4
Toxaphene	P123	8001-35-2
Warfarin (>0.3%)	P001	81-81-2
Zinc phosphide (>10%)	P122	1314-84-7

50 ACTIVES

II. PESTICIDES DERIVED FROM TRI-, TETRA-, AND PENTACHLOROPHENOLS [40 CFR 261.31]

2-Chloroethyl 2-(2,4,6-trichlorophenoxy) ethyl ether	F027	5324-22-1
Dehydroabietylammonium pentachlorophenoxide	F027	35109-57-0
Erbon	F027	136-25-4
O-ethyl O-(2,4,5-trichlorophenyl) ethylphosphonothioate	F027	327-98-0
2,2'-Methylenebis (3,4,6-trichlorophenol) (Hexachlorophene)	F027	70-30-4
--Potassium salt of	F027	67923-62-0
--Sodium salt of	F027	3247-34-5
--Disodium salt of	F027	5736-15-2
Pentachlorophenol	F027	87-86-5
--Potassium salt of	F027	7778-73-6
--Sodium salt of	F027	131-52-2
--Zinc salt of	F027	2917-32-0
--Zinc salt of N-alkyl (C_{16}-C_{18})-1,3-propanediamine	F027	
--Pentachlorophenyl laurate	F027	3772-94-9
Potassium trichlorophenate (2,4,6)	F027	2591-21-1
Potassium trichlorophenate (2,4,5)	F027	35471-43-3
Silvex	F027	93-72-1
--2-Butoxyethyl ester	F027	19398-13-1
--Butoxypolypropoxypropyl ester	F027	53404-07-2
--Butoxypropyl ester	F027	25537-26-2
--Diethanolamine salt	F027	51170-59-3
--Diisopropanolamine salt	F027	53404-09-4
--Dimethylamine salt	F027	55617-85-1
--Dipropylene glycol isobutyl ether ester	F027	53535-26-5
--Ethanolamine salt	F027	7374-47-2
--2-Ethylhexyl ester	F027	53404-76-5
--Isooctyl ester	F027	53404-14-1

--Isopropanolamine salt	F027	53404-13-0
--Monohydroxylaluminum salt	F027	69622-82-8
--Polypropoxypropyl ester	F027	83562-66-7
--Potassium salt	F027	2818-16-8
--Propylene glycol isobutyl ether ester	F027	53466-84-5
--Sodium salt	F027	37913-89-6
--Triethanolamine salt	F027	17369-89-0
--Triethylamine salt	F027	53404-74-3
--Triisopropanolamine salt	F027	53404-75-4
--Tripropylene glycol isobutyl ether ester	F027	53535-30-1
Sodium 2-(2,4,5-trichlorophenoxy) ethyl sulfate	F027	3570-61-4
Tetrachlorophenols	F027	25167-83-3
--Alkylamine*amine salt (as in fatty acids of coconut oil)	F027	
--Potassium salt	F027	53535-27-6
--Sodium salt	F027	25567-55-9
2,4,5-Trichlorophenol	F027	95-95-4
2,4,6-Trichlorophenol	F027	88-06-2
2,4,5-Trichlorophenol salt of 2,6-bis[(dimethylamino)methyl] cyclohexanone	F027	53404-83-4
2,4,5-Trichlorophenol, sodium salt	F027	136-32-3
2,4,6-Trichlorophenol, sodium salt	F027	3784-03-0
2,4,5-Trichlorophenoxyacetic acid	F027	93-79-8
--Alkyl C-12 amine salt	F027	53404-84-5
--Alkyl C-13 amine salt	F027	53404-85-6
--Alkyl C-14 amine salt	F027	53535-37-8
--N,N-diethylethanolamine salt	F027	53404-86-7
--Dimethylamine salt	F027	6369-97-7
--N,N-dimethyllinoleylamine salt	F027	53404-88-9
--N,N-dimethyloleylamine salt	F027	53404-89-0
--N-oleyl-1,3-propylene diamine salt	F027	53404-87-8
--Sodium salt	F027	13560-99-1
--Triethanolamine salt	F027	3813-14-7
--Triethylamine salt	F027	2008-46-0
--Alkyl (C_3H_7 - C_7H_9) ester	F027	
--Amyl ester	F027	120-39-8
--Butoxyethoxypropyl ester	F027	1928-58-1
--2-Butoxyethyl ester	F027	2545-59-7
--Butoxypropyl ester	F027	1928-48-9
--Butyl ester	F027	93-79-8
--Dipropylene glycol isobutyl ether ester	F027	53535-31-2
--2-Ethylhexyl ester	F027	1928-47-8
--Isobutyl ester	F027	4938-72-1

--Isopropyl ester	F027	93-78-7
--Propylene glycol isobutyl ether ester	F027	53466-86-7
--Tripropylene glycol isobutyl ether ester	F027	53535-32-3
4-(2,4,5-Trichlorophenoxy)butyric acid [2,4,5-TB]	F027	93-80-1
2-(2,4,5-Trichlorophenoxy)ethyl hydrogen sulfate [2,4,5-TES]	F027	69633-04-1
1,4',5'-Trichloro-2'-(2,4,5-trichlorophenoxy) methanesulfonanilide [Edolan U]	F027	69462-14-2

PEST/DIS-6

PESTICIDES THAT ARE TOXIC HAZARDOUS WASTES

PESTICIDES ON THE "F" LIST [40 CFR 261.33(f)]	(with RCRA #, and	CAS #
Acetone	U002	67-64-1
Acrylonitrile*	U009	107-13-1
Amitrole	U011	61-82-5
Benzene*	U019	71-43-2
Bis(2-ethylhexyl)phthalate	U028	117-81-7
Cacodylic acid	U136	75-60-5
Carbon tetrachloride*	U211	56-23-5
Chloral (hydrate) (chloroacetaldehyde)	U034	302-17-0
Chlordane, technical*	U036	57-74-9
Chlorobenzene*	U037	108-90-7
4-Chloro-m-cresol	U039	59-50-7
Chloroform*	U044	67-66-3
o-Chlorophenol	U048	95-57-8
Creosote	U051	8021-39-4
Cresylic acid (cresols)*	U052	1319-77-3
Cyclohexane	U056	110-82-7
Cyclohexanone	U057	108-94-1
Decachlorooctahydro-1,3,4-metheno-2H-cyclobuta[c,d]-pentalen-2-one (Kepone, chlordecone)	U142	143-50-0
1,2-Dibromo-3-chloropropane (DBCP)	U066	96-12-8
Dibutyl phthalate	U069	84-74-2
S-2,3-(Dichloroallyl diisopropylthiocarbamate) (diallate,Avadex)	U062	2303-16-4
o-Dichlorobenzene*	U070	95-50-1
p-Dichlorobenzene*	U072	106-46-7
Dichlorodifluoromethane (Freon 12®)	U075	75-71-8
3,5-Dichloro-N-(1,1-dimethyl-2-propynyl) benzamide (pronamide, Kerb®)	U192	23950-58-5
Dichloro diphenyl dichloroethane (DDD)	U060	72-54-8
Dichloro diphenyl trichloroethane (DDT)	U061	50-29-3
Dichloroethyl ether	U025	1191-17-9
2,4-Dichlorophenoxyacetic, salts and esters (2,4-D)*	U240	94-75-7
1,2-Dichloropropane	U083	8003-19-8
1,3-Dichloropropene (Telone)	U084	542-75-6
Dimethyl phthalate	U102	131-11-3
Epichlorohydrin (1-chloro-2,3-epoxypropane)	U041	106-89-8
Ethyl acetate	U112	141-78-6
Ethyl 4,4'-dichlorobenzilate (chlorobenzilate)	U038	510-15-6

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*Proposed for deletion by TCLP proposal

Ethylene dibromide (EDB)	U067	106-93-4
Ethylene dichloride*	U077	107-06-2
Ethylene oxide	U115	75-21-8
Formaldehyde	U122	50-00-0
Furfural	U125	98-01-1
Hexachlorobenzene*	U127	118-74-1
Hexachlorocyclopentadiene	U130	77-47-4
Hexachloroethane*	U131	67-72-1
Hydrofluoric acid	U134	7664-39-3
Isobutyl alcohol*	U140	78-83-1
Lead acetate	U144	301-04-2
Lindane*	U129	58-89-9
Maleic hydrazide	U148	123-33-1
Mercury	U151	7439-97-6
Methoxychlor*	U247	72-43-5
Methyl alcohol (methanol)	U154	67-56-1
Methyl bromide	U029	74-83-9
Methyl chloride	U045	74-87-3
2,2'-Methylenebis (3,4,6-trichlorophenol) (hexachlorophene) [acute waste per 261.31]	U132	70-30-4
Methylene chloride*	U080	75-09-2
Methyl ethyl ketone*	U159	78-93-3
4-Methyl-2-pentanone (methyl isobutyl ketone)	U161	108-10-1
Naphthalene	U165	91-20-3
Nitrobenzene*	U169	98-95-3
p-Nitrophenol	U170	100-02-7
Pentachloroethane	U184	76-01-7
Pentachloronitrobenzene (PCNB)	U185	82-68-8
Pentachlorophenol* [acute waste per 261.31]	U242	87-86-5
Phenol*	U188	108-95-2
Pyridine*	U196	110-86-1
Resorcinol	U201	108-46-3
Safrole	U203	94-59-7
Selenium disulfide	U205	7488-56-4
Silvex [acute waste per 261.31]	U233	93-72-1
1,1,2,2-Tetrachloroethane*	U209	79-34-5
Tetrachloroethylene*	U210	127-18-4
2,3,4,6-Tetrachlorophenol* [acute waste per 261.31]	U212	
Thiram	U244	137-26-8
Toluene*	U220	108-88-3
1,1,1-Trichloroethane* (methyl chloroform)	U226	71-55-6
Trichloroethylene*	U228	79-01-6
Trichloromonofluoromethane (Freon 11®)	U121	75-69-4
2,4,5-Trichlorophenol* [acute waste per 261.31]	U230	95-95-4
2,4,6-Trichlorophenol* [acute waste per 261.31]	U231	88-06-2

2,4,5-Trichlorophenoxyacetic acid (2,4,5-T)* [acute waste per 261.31]	U232	93-76-5
Warfarin (<0.3%)	U248	81-81-2
Xylene	U239	1330-20-7
Zinc phosphide (<10%)	U249	1314-84-7

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III. USE INDEX APPENDIX

45101

ALDRIN*

TYPE PESTICIDE: Insecticide

FORMULATIONS:
FI (25%)
EC (2 lb/gal, 4 lb/gal)

GENERAL WARNINGS AND LIMITATIONS: RESTRICTED USE PESTICIDE. Aldrin is toxic to fish and wildlife. Keep out of lakes, streams or ponds. During commercial or prolonged exposure in spraying, mixing and loading operation, wear clean rubber gloves. Wear a respirator jointly approved by the Mining Enforcement and Safety Administration (formerly the U.S. Bureau of Mines) and by the National Institute for Occupational Safety and Health under the provisions of 30 CFR Part II for aldrin protection. Do not apply aldrin in or around poultry houses, barns, silos, milk houses or other structures where livestock or poultry are held, or where food or feed is stored, prepared, or processed.

Agricultural Crop Tolerances:

Alfalfa	0.0 ppm
Apples	0.0 ppm
Apricots	0.0 ppm
Asparagus	0.1 ppm
Barley, Grain	0.02 ppm (interim)
Barley, Straw	0.1 ppm (interim)
Beans	0.0 ppm
Beets, Garden	0.0 ppm
Beets, Garden, Tops	0.0 ppm
Beets, Sugar	0.0 ppm
Beets, Sugar, Tops	0.0 ppm
Broccoli	0.1 ppm
Brussels Sprouts	0.1 ppm
Cabbage	0.1 ppm
Cantaloups	0.1 ppm
Carrots	0.0 ppm
Cauliflower	0.1 ppm
Celery	0.1 ppm
Cherries	0.1 ppm
Clover	0.0 ppm
Collards	0.0 ppm
Corn, Forage	0.0 ppm
Corn, Grain	0.0 ppm
Corn, Pop	0.0 ppm
Cowpeas	0.0 ppm
Cowpeas, Hay	0.0 ppm
Cranberries	0.1 ppm
Cucumbers	0.1 ppm
Eggplant	0.1 ppm
Endive (Escarole)	0.0 ppm
Garlic	0.0 ppm
Grapefruit	0.05 ppm (interim)
Grapes	0.1 ppm

*hexachlorohexahydro-endo, exo-dimethanonaphthalene 95% and related compounds 5%

GENERAL WARNINGS AND LIMITATIONS (continued)

Horseradish	0.0 ppm
Kale	0.0 ppm
Kohlrabi	0.0 ppm
Leeks	0.0 ppm
Lemons	0.05 ppm (interim)
Lespedeza	0.0 ppm
Lettuce	0.1 ppm
Limes	0.05 ppm (interim)
Mangoes	0.1 ppm
Muskmelons	0.1 ppm
Mustard, Greens	0.0 ppm
Nectarines	0.1 ppm
Oats, Grain	0.02 ppm (interim)
Oats, Straw	0.1 ppm (interim)
Onions	0.0 ppm
Oranges	0.05 ppm (interim)
Parsnips	0.0 ppm
Peaches	0.1 ppm
Peanuts	0.0 ppm
Peanuts, Hay	0.0 ppm
Pears	0.0 ppm
Peas	0.0 ppm
Peas, Black-eyed	0.0 ppm
Peas, Cowpeas	0.0 ppm
Peas, Hay	0.0 ppm
Peppers	0.1 ppm
Pimentos	0.1 ppm
Pineapples	0.1 ppm
Plums (Fresh Prunes)	0.1 ppm
Potatoes	0.1 ppm
Pumpkins	0.1 ppm
Quinces	0.0 ppm
Radishes	0.0 ppm
Rice, Grain	0.05 ppm (interim)
Rice, Straw	0.1 ppm (interim)
Rutabagas	0.0 ppm
Rye, Grain	0.02 ppm (interim)
Rye, Straw	0.1 ppm (interim)
Salsify, Roots	0.0 ppm
Salsify, Tops	0.0 ppm
Shallots	0.0 ppm
Sorghum, Forage	0.0 ppm
Sorghum, Grain	0.0 ppm
Soybeans	0.0 ppm
Soybeans, Hay	0.0 ppm
Spinach	0.0 ppm
Squash, Summer	0.1 ppm
Squash, Winter	0.1 ppm
Strawberries	0.1 ppm
Sweet Potatoes	0.1 ppm
Swiss Chard	0.0 ppm

GENERAL WARNINGS AND LIMITATIONS (continued)

Tangerines	0.05 ppm (interim)
Tomatoes	0.1 ppm
Turnips	0.0 ppm
Turnips, Tops	0.0 ppm
Watermelons	0.1 ppm
Wheat, Grain	0.02 ppm (interim)
Wheat, Straw	0.1 ppm (interim)

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	DOMESTIC OUTDOOR		
	(Wood or Wood Structure Protection Treatments)		
64000NA	Terrestrial Structures		
MGDAGA	Subterranean termites (including Coptotermes, Heterotermes, Reticulitermes, and Zootermopsis spp.)	0.25-0.5% emulsion (2, 4 lb/gal EC)	Soil contact wood protection treatment. Use limited to professional pest control operators. Apply the lower dosage (0.25 percent emulsion) for structures which should be inspected annually for possible reinfestation and retreatment if necessary. The higher dosage (0.5 percent emulsion) will give up to 8 years or more protection when used as directed. Annual reinspection is desirable to check areas possibly missed during initial treatment. These formulations are designed for treatment of soil to establish a barrier which is lethal to termites. Aldrin must be adequately dispersed in the soil to provide a barrier between the wood in the structure and the termite colonies in the soil or to control termites living in the structure. It is necessary for the effective use of aldrin that the service technician be familiar with current control practices including trenching, rodding, subslab injection, and low pressure spray application. These techniques must be correctly employed to prevent or control infestations by subterranean termite spe-

Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
Terrestrial Structures (continued)		
		cies of Coptotermes, Heterotermes, Reticulitermes and Zootermopsis. Choice of appropriate procedures includes consideration of such variable factors as the design of the structure, water table, soil type, soil compaction, grade conditions and location and type of domestic water supplies. The biology and behavior of the involved termite species are important factors to be known as well as suspected location of the colony and severity of the infestation within the structure to be protected. For advice concerning current control practices for specific local conditions, consult resources in structural pest control. Annual inspections of the treated area should be made. Soil should not be treated when excessively wet. The termites' source of moisture should be eliminated by providing a chemical barrier and/or repairing faulty construction. Contamination of public and private water supplies must be avoided by following these precautions: Use antiback-flow equipment or procedures to prevent syphonage of pesticide back into water supplies. Do not treat soil that is water saturated or frozen. Consult state and local specifications for recommended distances of treatment areas from wells, and refer to Federal Housing Administration (F.H.A.) Specifications for further guidance. All nonessential wood and cellulose containing materials, including scrap wood and form boards, should be removed from around foundation walls, crawl spaces, and porches.

Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations

Terrestrial Structures (continued)

PRECONSTRUCTION SUBTERRANEAN TERMITE TREATMENT

Effective preconstruction subterranean termite control requires the establishment of an unbroken vertical and/or horizontal chemical barrier between wood in the structure and the termite colonies in the soil. To meet F.H.A. termite proofing requirements, follow the latest edition of the Housing and Urban Development (H.U.D.) Minimum Property Standards. After grading is completed and prior to the pouring of the slab, slab supported/constructed porches, or entrance platforms, make the following treatments. Applications shall be made by a low pressure spray for horizontal barriers over areas intended for covering floors, porches, and other critical areas. Establish a vertical barrier in areas such as around the base of foundations, plumbing, back-filled soil against foundation walls, and other critical areas.

1. Where it is necessary to produce a horizontal barrier, apply the emulsion at the rate of 1 gallon of emulsion per 10 square feet to dirt fill. If fill is washed gravel or other coarse material, apply at 1.5 gallons of emulsion per 10 square feet. It is important that the emulsion reaches the soil substrate.
   a. If concrete slabs cannot be poured over soil the same day it has been treated, a waterproof cover, such as polyethylene sheeting, should be placed over the soil. This is not necessary if foundation walls have been installed around the treated soil.

Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations

Terrestrial Structures (continued)

2. To produce a vertical barrier, apply the emulsion at the rate of 4 gallons of emulsion per 10 linear feet per foot of depth.
   a. Rodding and/or trenching applications should not be made below the top of the footing.
   b. Trench need not be wider than 6 inches.
   c. Rod holes should extend from the base of the trench to the top of the footing, and should be spaced (about 1 foot) to provide a continuous barrier.
   d. Emulsion should be mixed with the soil as it is being replaced in the trench. Cover treated soil with a layer of untreated soil.
3. Hollow block foundations or voids of masonry should be treated to make a continuous chemical barrier in voids. Apply at the rate of 2 gallons of emulsion per 10 linear feet so it will reach the footing.
4. For crawl spaces apply at the rate of 4 gallons of emulsion per 10 linear feet per foot of depth from grade to bottom of foundations. Application may be made by rodding, low pressure spray, and/or trenching. Treat both sides of foundation and around all piers and pipes.
   a. Rod holes should be spaced (about 1 foot) to provide a continuous chemical barrier.
   b. Trench need not be wider than 6 inches nor below the foundation. The emulsion should be mixed with the soil as it is being replaced in the trench. Cover the treated soil with a layer of untreated soil.

Site and Pest | Dosages and Formulation(s) | Tolerance, Use, Limitations

Terrestrial Structures (continued)

c. Do not apply in any manner to an area intended as a plenum air space.

d. Do not apply as an overall treatment to soil in crawl spaces.

All holes drilled in construction elements for treatment should be securely plugged.

POSTCONSTRUCTION TREATMENTS

Postconstruction applications shall be made by injection, rodding, low pressure spray, and/or trenching. Do not apply emulsion until location of heat or air conditioning ducts, vents, water and sewer lines, or electrical conduits are known and identified. Extreme caution must be taken to avoid contamination of these structural elements and airways. Do not apply in any manner to an area intended as a plenum air space.

1. For slab-on-ground construction apply at the rate of 4 gallons of emulsion per 10 linear feet. Application may be made by sub-slab injection. Injectors should not extend beyond the tops of the footings. Treat along the outside of the foundation and where necessary on the inside of foundation walls. Treatment may also be required along 1 side of interior partitions and along all cracks and expansion joints.
    a. Drill holes in the slab to provide a continuous chemical barrier.
    b. Where necessary, drill through the foundation walls from the outside and force the emulsion just beneath the slab or along all the cracks and expansion joints and other critical areas.

Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations

Terrestrial Structures (continued)

c. For shallow foundations, 1 foot or less, dig a narrow trench approximately 6 inches wide along the outside of the foundation walls. Do not dig below the bottom of the foundation. The emulsion should be applied to the trench and the soil at the rate of 4 gallons of emulsion per 10 linear feet as the soil is replaced in the trench. Cover the treated soil with a layer of untreated soil.

d. For foundations deeper than 1 foot follow rates for basements.

2. Hollow block foundations or voids of masonry should be treated to make a continuous chemical barrier in voids. Apply at the rate of 2 gallons of emulsion per 10 linear feet.
3. For basements apply at the rate of 4 gallons of emulsion per 10 linear feet. Where footings are greater than 1 foot of depth from the grade to the bottom of the foundation, application may be made by trenching and/or rodding. Treat outside of foundation walls, and if necessary along inside of foundation walls, along cracks in basement floors, along interior load bearing walls, around sewer pipes, conduits, and piers.
4. In crawl spaces apply at the rate of 4 gallons of emulsion per 10 linear feet per foot of depth from grade to bottom of foundation. Application may be made by rodding, and/or trenching. Treat both sides of foundation and around all piers and pipes.

Site and Pest | Dosages and Formulation(s) | Tolerance, Use, Limitations

Terrestrial Structures (continued)

a. Rod holes should be spaced (about 1 foot) to provide a continuous chemical barrier.
b. Trench need not be wider than 6 inches nor below the foundations. The emulsion should be mixed with the soil as it is replaced in the trench. Cover the treated soil with a layer of untreated soil.
c. Do not apply in any manner to an area intended as a plenum air space. After treatment, securely plug all holes drilled in construction elements.
d. Do not apply as an overall treatment to soil in crawl spaces.

- All holes drilled in construction elements for treatment should be securely plugged.

RETREATMENT RESTRICTIONS

Retreatment for subterranean termites should only be made when there is evidence of reinfestations subsequent to the initial treatment, or there has been a disruption of the chemical barrier in the soil due to construction, excavations, or landscaping. Reapplication should be made as a spot treatment to these areas. Avoid annual retreatment of the entire premises.

INDOOR

(Wood or Wood Structure Protection Treatments)

/64000NA Terrestrial Structures

Refer to DOMESTIC OUTDOOR, (Wood or Wood Structure Protection Treatments), Terrestrial Structures.

Listing of Registered Pesticide Products by Formulation

025.0002 25% formulation intermediate
aldrin (045101)
002459-00201*
*suspended

102.0012 2 lb/gal emulsifiable concentrate
aldrin (045101)
037686-00005

aldrin (045101) plus aromatic petroleum distillate (006601)
001842-00163 001842-00282

104.0012 4 lb/gal emulsifiable concentrate
aldrin (045101)
001927-00022

aldrin (045101) plus aromatic petroleum derivative solvent (006501)
001022-00220 009859-00254*
*suspended

aldrin (045101) plus heavy aromatic naphtha (006602)
006720-00188

aldrin (045101) plus petroleum distillate (063503)
003743-00308 008915-00002

aldrin (045101) plus xylene (086802)
001842-00134

aldrin (045101), kerosene (063501) plus xylene (086802)
004887-00027

IV. BIBLIOGRAPHY APPENDICES

BIBGUIDE-1

GUIDE TO USE OF THIS BIBLIOGRAPHY

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission Date. The date of the earliest known submission appears immediately following the word "received."

(2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registrations under the Aldrin Standard

00003503 Johnson, W.W.: Finley, M.T. (1980) Handbook of Acute Toxicity of Chemicals to Fish and Aqiatic Invertebrates. U.S. Dept. of the Interior, Fish and Wildlife Service, Resource Publication 137:134.

00020560 Schafer, E.W. (1972) The acute oral toxicity of 369 pesticidal, pharmaceutical and other chemicals to wild birds. Toxicology and Applied Pharmacology 21(?):315-330. (Also In unpublished submission received Apr 25, 1978 under 476-2180; submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:233577-C)

00022923 Hill, E.F.; Heath, R.G.: Spann, J.S.; et al. (1975) Lethal Dietary Toxicities of Environmental Pollutants to Birds: Special Scientific Report--Wildlife No. 191. (U.S. Dept. of the Interior, Fish and Wildlife Service, Patuxent Wildlife Research Center; Unpublished report)

00059894 Treon JF and Cleveland FP. 1955, Toxicity of certain chlorinated hydrogen insecticides for laboratory animals, with special reference to aldrin and dieldrin. Agric. Food Chem. 3:402-408.

00072077 Treon, J.F.; Cleveland, F.P. (1954) The Toxicity of Certain Chlorinated Hydrocarbon Insecticides with Special Reference to Aldrin and Dieldrin. (Unpublished study received Mar 3, 1955 Under PP0007; prepared by Univ. of Cincinnati, Dept. of Preventive Medicine and Industrial Health, Kettering Laboratory, submitted by Shell Chemical Corp., New York, N.Y.; CDL:090079-J)

00083074 Treon, J.F.: Boyd, J.; Berryman, G.; et al. (1954) Final Report on the Reproductive Capacity of Three Generations of Rats Being Fed on Diets Containing Aldrin, Dieldrin or DDT. (Unpublished study received Mar 3, 1955 under PP0007; prepared by Univ. of Cincinatti, Dept. of Preventive Medicine and Industrial Health, Kettering Laboratory, submitted by Shell Chemical Corp., New York, N.Y.; CDL:090080-R)

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registrations under the Aldrin Standard

00085416	Borgmann, A.R.; Kitselman, C.H.: Dahm, P.A.; et al. (1952) Toxicological Studies of Aldrin on Small Laboratory Animals. (Unpublished study received March 3, 1955 under PP0007; prepared by Kansas State College, Agricultural Experiment Station, Depts. of Entomology and Pathology and Univ. of Cincinatti, Dept. of Pathology, Kettering Laboratory of Applied Physiology, submitted by Shell Chemical Corp., New York, N.Y.; CDL:090087-B)
00103597	Lichtenstein, E. (1958) Movement of insecticides in soils under leaching and non-leaching conditions. Journal of Economic Entomology 51 (Jun):380-383. (Also in unpublished submission received Oct 1, 1971 under 1F1070; submitted by Shell Chemical Co., Washington, DC; CDL:091958-AK)
00103661	Lichtenstein, E.; Schulz, K.; Skrentny, R.; et al. (1966) Toxicity and fate of insecticide residues in water: Insecticide residues in water after direct applications or by leaching of agricultural soil. Arch Environ Health 12(Feb):199-212. (Also in unpublished submission received Dec. 20, 1968 under 9F0785; submitted by Shell Chemical Co., Washington, DC; CDL:091349-T)
00103736	Treon, J.; Dutra, F.; Shaffer, F.; et al. (1951) The Toxicity of Aldrin, Dieldrin and DDR when Fed to Rats over the Period of Six Months. (Unpublished study received Dec 3, 1951 under unknown adin. no.; prepared by Univ. of Cincinatti, Dept. of Preventive Medicine and Industrial Health, Kettering Laboratory, submitted by Shell Chemical Co., Washington, DC; CDL:106797-A)
00105470	Keplinger, M.: Deichmann, W.: F. Sala. (1970) Effects of combinations of pesticides on reproduction in mice. Pesticides Symposia (August) 125-138.
00109564	Probst GS, McMahon RE, Hill LW, Thompson DZ, Epp JK, Neal SB. 1981. Chemically-induced unscheduled DNA synthesis in primary rat hepatocyte cultures: a comparison with bacterial mutagenicity using 218 chemicals. Environ. Mutagenesis 3:11-32.

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registrations under the Aldrin Standard

00111910 Tucker, R; Crabtree, D. (1970) Handbook of Toxicity of Pesticides to Wildlife. Resource Publication No. 84, Bureau of Sport Fisheries and Wildlife, Denver Wildlife Research Center. Denver, CO.

00123771 Epstein, S.; Arnold, E.; Andrea, J; Bass, W.; Bisphop, Y. 1972. Detection of Chemical Mutagens by the Dominant Lethal Assay in the Mouse. Toxicol. and Appl. Pharmacol. 23 (288):288-325.

00151668 Ludwig, G.; Weis, J.; Korte, F. (1964) Excretion and Distribution of Aldrin-^{14}C and its Metabolites After Oral Administration for a Long Period of Time. Life Sciences 3:123-130.

00151872 Deichmann, W.; Keplinger, M. Dressler, I.; et al. (1969) Retention of dieldrin and DDT in the tissues of dogs fed aldrin and DDT individually and as a mixture. Toxicology and Applied Pharmacology 14:205-213.

00151879 Deichmann, W.; MacDonald, W.; Cubit, D. (1975) Dieldrin and DDT in the Tissues of Mice Fed Aldrin and DDT for Seven Generations. Arch. Toxicol. 34:173-182.

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registration under the Aldrin Standard

GS0172-001 Page, N.; Cavender, F.; Cook, B. (1985) Carcinogenic Risk Assessment for Aldrin and Dieldrin. Unpublished study prepared by Dynamac Corp. under EPA Contract No. 68-02-4131.

GS0172-002 Environmental Protection Agency. Lauber, M. 1986. Lab Recommendation for Retrospective Studies Concerning Surface Water Contamination as a Result of Termiticide Use of Chlorinated Cyclodienes. Memo to Michael Firestone dated June 10, 1986.

GS0172-003 Environmental Protection Agency. Mauer, I. 1986. Aldrin/Dieldrin Mutagenicity. Memo to Henry Spencer dated 6-25-86.

V. FORMS APPENDICES

OMB Approval No. 2000-0468 (Expires 12-31-83)

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET	**EPA REGISTRATION NO.**

PRODUCT NAME

APPLICANT'S NAME	**DATE GUIDANCE DOCUMENT ISSUED**

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

Attach separate page with a list of the data requirements your company agrees to satisfy.

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

Attach list of data requirements

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE	**SIGNATURE**	**DATE**

EPA Form 8580-1 (10-82)

OMB Approval No. 2000-0468 (Expires: 12-31-83)

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(To qualify, certify ALL four items)

GUIDANCE DOCUMENT DATE

ACTIVE INGREDIENT

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:

NAME OF FIRM	EPA COMPANY NUMBER

(This firm or group of firms is referred to below as "my firm".)

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

NAME OF FIRM	DATE OF OFFER

However, none of those firm(s) accepted my offer.

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

TYPED NAME	SIGNATURE	DATE

EPA Form 8580-6 (10-82)

PRODUCT SPECIFIC DATA REPORT

EPA Reg. No.____________________ Date __________________________

Guidance Document for ____

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	
§158.120 PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	(For EPA Use Only) Accession Numbers Assigned
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
§158.135 TOXICOLOGY					
81-1	Acute oral toxicity, rat				
81-2	Acute dermal toxicity, rabbit				
81-3	Acute inhalation, toxicity, rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

843/10

FORMULATOR'S EXEMPTION STATEMENT
(40 CFR 152.85)

EPA File Symbol/Reg. No. ____________ Product Name ____________________

Applicant's Name and Address ____________________________________

____

____

____

As an authorized representative of the applicant for registration of the product identified above, I hereby certify that:

(1) This product contains the active ingredient(s): _______________

____

____

(2) Each active ingredient listed in paragraph (1) is present solely as the result of the incorporation into the product (during formulation or packaging) of another product which contains that active ingredient, which is registered under FIFRA sec. 3, and which is purchased by us from another producer.

(3) Indicate by circling (A) or (B) below which paragraph applies:

(A) An accurate Confidential Statement of Formula (EPA Form 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

(B) The Confidential Statement of Formula dated __________ on file with the EPA is complete, current and accurate and contains the information required on the current CSF Form No. 8570-4. The registered source(s) of the active ingredient(s) listed in paragraph (1) is/are listed below:

Active ingredient	Source: Product name and Reg. No.

Signature ______________________________

Date ______________ Title ______________________________

EPA Form (April 1985)